PCAST Workgroup
Draft Transcript
March 17, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody and welcome to the PCAST Workgroup. This is a Federal Advisory Committee so there will be opportunity at the end of the call for the public to make comment. A reminder, please, for the workgroup members to identify yourselves for attribution.

Let me do a quick roll call. Paul Egerman?

Paul Egerman – Software Entrepreneur
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Bill Stead?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Steve Ondra?

Stephen Ondra – NeHC – Senior Policy Advisor
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Halamka? Dixie Baker?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Wes Rishel? Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Leslie Harris? Bob Kahn?

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Gary Marchionini?

Gary Marchionini – University of North Carolina – Dean & Professor
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Richard Platt? Carl Gunter? Hunt Blair?

Hunt Blair – OVHA – Deputy Director
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Tim Elwell?

Tim Elwell – Misys Open Source Solutions – Vice President
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Steve Stack?

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Mark Rothstein? Eileen Twiggs? Jonathan Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Did I leave anybody off? Okay, with that I'll turn it over to Paul Egerman and Bill Stead.

Paul Egerman – Software Entrepreneur
Good morning. I want to welcome you to our PCAST Workgroup Conference call. The PCAST Workgroup was formed shortly after PCAST, which is an advisory council to the president, issued a report in December, called "The Path Forward" related to HIT and information exchange. I'll talk in a minute about what our basic charge is.

What you see on the screen is our agenda for today. For today, there are three major things we have to do. You see item number three is "Review the Implementation Taskforce." The Implementation Taskforce was a group of about half a dozen individuals who did some really very impressive excellent work over the past couple of weeks, going through some examples of how we would implement the recommendations or the basic concepts from the PCAST Report. The second thing that we need to get accomplished this morning is a review of the Policy Taskforce, which is again another group of about half a dozen people who met and talked about policies.

Then you see number five on the agenda on your screen "Stage Two of Meaningful Use." I do want to quickly explain to the members of the workgroup who may not be involved with ONC right now, is stage two of meaningful use is a topic that I would call is on the front burner for ONC right now. In other words, at the end of March, beginning of April into mid-April, this is a major topic as to what is the plan for stage two of meaningful use because of the whole regulatory cycle that a lot of the decisions need to be made. So it takes us a little bit out of our sequence, but it's most important in this call that we have a clear sense from the PCAST Workgroup of what are the alternatives for stage two of meaningful use.

Then the next item on the agenda to review is to "Review Section C Graph." This is something that Bill and I sent out. It's a review of a little bit of what we discussed last time, but it's also some straw man suggestions. It would be great if we could get that far today. I know there are a lot of academic people who are participants in the call, if we get that far you should give us all extra credit or a star or something, because that would be significant to get that far in the agenda.

Those are the agenda items. After that, of course, we will have public comment. Members of the public who are listening I want to tell you that your comments are critically important, especially as we go

through some of these issues like the Implementation Taskforce, issuing the policy issues. We very much would like to get feedback and suggestions to make sure that what we're doing is correct.

I'm going to talk about the charge in a minute, but are there any questions about the agenda? Great. Here are the members of the workgroup. Like all ONC workgroups this is a really excellent membership, so I want to, again, thank the members for participating in this call. I know it's a lot of work for everybody participating. I want to especially thank those of you, like Dixie, who are out on the west coast. I know it's 7:00 in the morning out there, and so I very much appreciate your dedication.

This briefly is again our charge, the PCAST Report Workgroup, there are a lot of words on this screen, but to try to summarize it, we are charged with understanding and analyzing public comments about the report and we're charged with discussing the implications of the report and the feasibility of the report on current ONC strategies and programs. It's important to remember that our charge does not include criticizing the report. We're not involved with saying whether or not the report is good or bad or right or wrong, and we are not really saying well, here's a totally different way to do things. Our focus is understanding the report, understanding the basic directions it suggests, and discussing how ONC might implement that.

One more thing is to make sure that everybody understands the schedule. These are our meeting dates. It says March 17th, so that's today's meeting. We have one more meeting at the end of March, scheduled for March 30th. This schedule is oriented toward completing our work in March so that on April 13th we can produce a final report to the HIT Policy Committee. That's our goal. So we have today's meeting and one more meeting on the 30th, and in between that probably several hundred e-mails in terms of how we can get our work done. Those are our meeting dates.

The first, unless people have some comments, the first agenda item is the report for the Implementation Task Group. Dr. Stead, would you like to take us through that?

William Stead – Vanderbilt – Chief Strategy and Information Officer

Thank you, Paul. The Implementation Taskforce was Dixie Baker, Carl Gunter, John Halamka, Stan Huff, Wes Rishel, and myself. We were asked to develop two or more illustrative examples of implementation approaches to achieve the directions and vision about PCAST so that we could see what we mean by an approach, by that I mean how the different components work together and so that we could see what they had in common. We developed three use cases, which have been e-mailed to the workgroup and I believe by now posted for the call. They correspond to three levels of exchange. We included a fourth use case that deals with de-identified data, but I want to direct our time today to the three cases that involve direct patient care.

We describe the first use case as push by the patient between two points. In this case, the patient would log on to their tethered PHR, the PHR that's related to their provider's portal, if you will, with their user name and password that's based on the organization that provides that portal. They will choose to push the data to the non-tethered PHR of their own choice, and there are many ways that that can be done that are currently commercially available. In each case the data would be wrapped in a uniform exchange language envelope that contained identify information, provenance information, and privacy information. When that packet arrived at their non-tethered PHR it would be shown to the patient, who could then elect to incorporate it in structure or unstructured form into their untethered PHR data set. Then they're in a position to decide which clinicians, researchers, etc., to share it with, and if they share it they push it to them in a UEL envelope via secure transmission, such as the current direct infrastructure to the recipients of their choice.

The second use case we described as "simple search." A patient, for example, could present to the emergency room and they could say that their records are held at a particular hospital or clinic. The emergency physician could then obtain the patient's consent to retrieve their record and a query would be created that included their identity consent and authentication data, and then an indexing and search service would be used to find out the Uniform Resource Identifier of that clinician's office or hospital. So it's going to a known entity and the search is simply finding out what's the network address of that entity.

The query would then go to that entity and it would return a UEL wrapped set of data containing the identity, provenance and privacy metadata based on the consents that are on file at the organization holding the record, and it's that organization that's in fact responding to the search. The content inside that packet, the clinical content, includes numerous clinical vocabularies, etc., and the receiving clinician could then elect to incorporate structured and unstructured REC data into their own ED record.

The third example is what we called "complex search." In this case, the patient would present to the emergency room non-responsive. However, there would be an ID in their wallet that had name and date of birth. The emergency physician, based on policy, which grants implied consent for unconscious patients, could then click on the external search icon in their local EHR, and that EHR could create a query containing the patient's identity implied consent provider authentication enroll and send that to a data element access service, the indexing search capability in PCAST.

The DEAS would then return a list of uniform resource identifiers of organizations, which hold the patient's record, and the emergency physician's EHR could then send a query containing identity consent information provider authentication enrolls to those network addresses and request problems, medications, allergies, etc. Each organization would return as many of the UEL packages as match their privacy metadata based on consents they have on file and the clinical request. That packet would then come back and the receiving EHR would be able to filter it, organize it, and present it to the clinician, who can elect to incorporate it in whatever form they wanted to in the local ED record, but as they did that it would bring along with it privacy, provenance, etc., metadata.

Leslie Harris – Center for Democracy & Technology – President & CEO
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William Stead – Vanderbilt – Chief Strategy and Information Officer
So those were the three high level examples. I'm sorry?

Leslie Harris – Center for Democracy & Technology – President & CEO
I just want to make sure I understand something. When you're talking about how a universal exchange … metadata includes a variety of information here, is that metadata exposed in the index, or only available to recipients who have already been granted access to the content?

William Stead – Vanderbilt – Chief Strategy and Information Officer
It depends on which level of exchange you're talking about. So if you'll give me a chance to get at that, because each of them is quite different.

Leslie Harris – Center for Democracy & Technology – President & CEO
Okay.

William Stead – Vanderbilt – Chief Strategy and Information Officer
The next thing we did, if you can flip to the technical framework components, is then to identify at high level the 15 components or capabilities, if you will, that would need to work together in some form to support the type of use cases that we described. Because we first are left to understand the components and then let's see what each of those components would look like in the different situations of the use cases, what does the end user need to do, the actual person, what does the local system, their electronic health record need to do.

Then with the UEL, first we defined the UEL as the syntax that captures the logical structure of the clinical data and that binds any coded data in the clinical packet to the standard terminologies and ontologies, etc. Because of that definition, we then said the UEL itself actually has four major components: its syntax, the structure, then the required metadata, by which we mean the semantic standards for privacy, provenance, and identity metadata. Then a naming authority, which would be a service that would manage the naming and versioning of the UEL syntax, the metadata semantics, the clinical data structure such as the CCD and clinical data semantics and then the mechanism of the binding.

For the index and search service our report includes a schematic which Dixie and Carl iteratively developed, which I think is a very useful picture of what a full function DEAS might actually look like, and it actually shows that each query response would involve ten steps. For the purposes of this table, we simplified that to what the service needs to do, what the sources that hold data would have to do to respond to the service, the privacy implications of the above, and the aspects of the query language that would be necessary. Then the additional parts of work are the mechanism for achieving separation of duties, which is in essence controlled by having one person not control too many pieces of the problem, you separate who can actually deal with each piece, how you deal with audit authentication for both patients and providers, and then the policy implications of the framework.

If you can go to the slide that shows the index search detail for the three levels—

Paul Egerman – Software Entrepreneur
Not to interrupt you, Bill, but before you go on to the next slide I just want to say this technical framework ... so this is by itself a very significant piece of work. This is great, the fact that we have now defined a framework to proceed, so great work.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you. What we then did was take the three use cases and we said what each component would need to be able to do to support that use case. What this table shows you is that in fact what that turned into was three levels of progressive support for exchange. In the first level, all exchange would be done within the context of a PHR and it would live within the context of our existing policies. In the second level, the search would need to be able to locate known sources and at that juncture, you would begin to be adding a DEAS capability, but it would be an extremely thin one. I'm getting playback.

Paul Egerman – Software Entrepreneur
Yes, somebody perhaps needs to put their phone on mute. Thanks. Try again, Bill.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Okay. It adds DEAS, but it's an extremely thin DEAS because all it needs to do is be able to find the location of the person holding the record. But it does add new policy and governance constraints and it adds the need for the capability to disambiguate identity.

The third level, which would represent what we see as the PCAST end state, would take the full definition of each of the components and all the related policy pieces that would be necessary to make it work. I think the key ahas that the taskforce came out with as we went through this work were first, we do need to think of the technical framework as a set of components, each of which have to work together. We cannot define one in isolation. As we define one it changes what's required of the others, and that's an important idea.

The second important idea is that as we looked at it we didn't actually start this way but we discovered that what we started out doing as three alternatives were actually three progressive levels. That is very powerful because it means that instead of having to be forced to pick one and live with the pros and cons of that one, we actually could elect to start with the first, which largely lives within stuff we know how to do. Then we could progress to the second and the third, over time, as the various combination of components were proven through test beds and pilots.

To re-highlight that point again, in fact, the three use cases are not mutually exclusive. They in fact can interoperate. For example, if all three were supported, the patient in use case one could use a simple search of use case two to query for the URIs of a provider they would like to push their information to. Then they could use the complex search of use case three to expose a UEL wrapped subset of their PHR to the DEAS tagged with privacy tags indicating their desire that it be made available to someone giving them care and a provenance tag indicating that he or she had ... it.

So at high level, that's the framework that the taskforce developed. Do any of the members of the taskforce want to clarify, or did I cover that okay?

Gary Marchionini – University of North Carolina – Dean & Professor
I just also want to compliment you for pulling this together in such a clear way. I thought that diagram was extremely helpful, and this explanation really helps, so nice work.

Paul Egerman – Software Entrepreneur
Bill, did you want to do the two definitions on the next slide?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Yes. We'll then close with a definition. I had already walked through the definition of the UEL, but the other thing we talked a lot about was atomic and in the end what we're basically saying is the smallest meaningful piece of information about a patient, so that that could be a note, it could be a prescription. It's whatever is, in fact, meaningful.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Bill, I just wanted to make one comment about the description of complex search. I agree that you guys have done quite a bit of work in a very short time. There are different ways you can interpret your level three complex search description, so what I wanted to do was just give you a sense of a way to interpret it that you may have meant but it doesn't leap out immediately. It seems to me that one way to interpret all of that is rather than figuring out in advance how to structure everything in terms of queries that are going on, that you could have the query be a very generic structure that every query would take because it was flexible enough to accommodate anything now or in the future. In other words, it's evolvable, and that everything in that query structure is based on identifiers, so that the critical component then becomes a resolution mechanism to resolve those identifiers to figure out what they mean in each context and all the semantics could be taken off line and be the result of this resolution process. So even though you might have something that's very specific to a given type of disease or patient or query or whatever, you could figure that out by these resolution steps, which are trying to parse what that query is.

Now, when I heard you describe that, I kept thinking that in the back of my mind, but I realize that other people might not get that particular model out as well. So I'm just wondering whether that's something you think is clarifying or just let people make their own judgments as to what that third part of complex search really is.

William Stead – Vanderbilt – Chief Strategy and Information Officer
I think those are good points. I didn't walk through all the statements in the use cases. Our intent was that the clinical data, for example, could contain any variety of semantics as long as there was a service that kept track of the naming and versioning of the semantics that were in use in different places so that a recipient could go to that service and get the information they needed to decode it. I think you're quite right; our thought is that the indexing service has nothing but metadata, and that metadata is largely non-disclosing.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Okay, well it sounds like you had some of those ideals in your head and I was just not sure whether everybody else would have gotten that same ....

William Stead – Vanderbilt – Chief Strategy and Information Officer
Any help you can give us as we go through the editing to bring those things out will be helpful.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
....

Tim Elwell – Misys Open Source Solutions – Vice President
Bill, I think this is great. This helps, I think, pull together a lot of the questions that I had previously. When I look at the diagram, one of the things that I was curious about, in your discussion with the group, was there an expectation, perhaps it's implied in the diagram, at the central service for DEAS that there would be either a policy service or an audit service that would be centrally located?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Does somebody smarter than me want to address that?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, it would. Yes, there would be, and that's a really good point, actually. One of the things that I think is important is that every query to the DEAS is accompanied by the authenticated and authorized identity of the querier and their role, and so all of that needs to be checked at the DEAS. So, yes, there is a policy mediation component and every query and its results are audited at the DEAS as well.

William Stead – Vanderbilt – Chief Strategy and Information Officer
I've got to drop off. I'm sorry.

Carl Gunter – University of Illinois – Professor
I think an interesting feature of this is that the DEAS both has a lot of access to metadata so that this raises privacy concerns, but at the same time it has a lot of access to data that would lead to effective audit. So you gain a powerful information element when you use this approach.

Tim Elwell – Misys Open Source Solutions – Vice President
I agree. I'm just curious, though, for instance if I were to liken this to something that I understand today with IHE there would be a profile that would be identified typically as a centralized service and oftentimes that's identified as a discrete element. Instead of it being implied, perhaps it needs to be discrete.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I agree. I'll make sure that that's done, Tim. I think that that's a really good comment.

Paul Egerman – Software Entrepreneur
The important thing for the workgroup members is to please state your name before you speak so the listeners will know who's speaking.

Leslie Harris – Center for Democracy & Technology – President & CEO
I got cut off, I'm guessing, at the key moment here where we were discussing how much data was in this metadata and answering the question that I posed before about that data being available while you're searching or when you've been authorized. Am I correct that there's a lot of data here, the metadata, the way I'm looking at this?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

Leslie Harris – Center for Democracy & Technology – President & CEO
Okay. It does concern me quite a bit.

Paul Egerman – Software Entrepreneur
Yes, and Dixie and Carl see if I've got this right, there is a lot, although it's a lot when you get to the progression. There's none in—

Carl Gunter – University of Illinois – Professor
There could be a lot in the third case.

Paul Egerman – Software Entrepreneur
Yes, in the third case.

Carl Gunter – University of Illinois – Professor
There could be a lot in the third case.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

There's a lot, but one of the comments that I wanted to make sure was real clear, and I don't think it was real clear from Bill's excellent description, is he mentioned that patients would be able to query the DEAS. I don't think that that's clear because the PCAST Report makes it very clear, and my understanding of the description that really was the source of the diagram we created, is that every user of the DEAS is authenticated and is authorized in a particular role. So the DEAS is not like a random store of metadata that anybody can come and search. I think that's a really, really important point.

Leslie Harris – Center for Democracy & Technology – President & CEO
It is, Dixie, but if I'm authorized because I'm a doctor somewhere that doesn't mean I'm authorized for every person in the country.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Well, that's part of your role. You're the doctor for a particular person and you're a particular type of doctor for a particular person. That's the nature of roles. They're not just "I'm a doctor."

Paul Egerman – Software Entrepreneur
I just want to take this discussion up a level, as it were. To be clear in terms of your question, Leslie, there is this progression. What the Implementation Taskforce has put forward is three levels. The first level really involves no DEAS and no metadata. It's really focused on the universal exchange language. The second level involves a DEAS record locator, which just locates the record but does not have metadata in the search. The third level is the level where there are the concerns that you are talking about.

Leslie Harris – Center for Democracy & Technology – President & CEO
Exactly. It's the third level that I have these—

Paul Egerman – Software Entrepreneur
That's correct. We'll talk in a minute about how we're going to interrelate policy issues with the technology issues.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Paul, at that second level, even the patient names aren't in the directory. It's really a directory of providers. You'll recall that the use case is that the person comes into the ED and says my record is over here at Kaiser, and so they would look up in the directory the doctor for that and request that information. So you're not even searching for patients there.

Paul Egerman – Software Entrepreneur
Dixie, thank you for correcting me on that. Apparently, Bill had to drop off, and so once he dropped off and I started answering the questions there was a significant drop in expertise also, so that is correct. I appreciate that correction. The second level does have any patient identification material. It would just say, for example, "Kaiser is at location 123456."

John Halamka – Harvard Medical School – Chief Information Officer
Just to clarify that, because that's so important, is obviously just your presence of a record at a given institution can be disclosing if it's a mental health facility, an abortion clinic, etc. So this truly isn't a DEAS in level two, it's really more an entity level provider directory. But we really want to just illustrate the point that any such infrastructure that would be necessary to provide even the simplest query you need to know where to look assuming a patient has told you an institutional name.

Leslie Harris – Center for Democracy & Technology – President & CEO
Right.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
John, I think that's a really important point. What it sounds to me—and just correct me if I'm wrong here—is that as I look at level one and level two there are two pieces that are going to be required. There's going to have to be some way of identifying a person, because that's how you're going to be able

to get the digital certificates, if you will, to be able to do the encryption on either end, and it could be a person or it could be an organization, depending on how the structure is done. To Dixie's point, there needs to be someplace where you can find out what a person, once you've identified them, what they're authorized to do. So that suggests that not only are we going to have to have some mechanism to manage the digital certificates, but we'll also need to have something that provides either an entity or a provider directory that provides that kind of information.

John Halamka – Harvard Medical School – Chief Information Officer
Correct.

Paul Egerman – Software Entrepreneur
John, I don't think you need digital certificates for the first level.

John Halamka – Harvard Medical School – Chief Information Officer
The question, of course, here is given that there are data exchanges taking place, I think maybe you're correct. If you don't need a person identified digital certificate in the sense that we are talking about for the Direct Project or other aspects of exchange where you're using client side certs, I mean, certificates will be used to encrypt the communication. There is really very thin infrastructure for level one, basically nothing beyond what we already have. Level two introduces an entity level provider directory, which, as you guys have suggested, is going to presumably include organizational type certificates to protect data integrity and encrypt the channel. I need to do an identification of the patient and disambiguation of the patient purely for the query to the organization providing the data, not for any metadata or index in the center.

Paul Egerman – Software Entrepreneur
To get back to Doug's question, for level one my understanding is we have the various components pretty much in place in terms of identification for that. We have to define some issues related to the UEL. It's when you get to level two is when we start to get to individual certificates, and because it's query responsive we also start to get to some more policy issues that we don't yet have in place. Is that correct, John?

John Halamka – Harvard Medical School – Chief Information Officer
Correct. That is, you can assume that given the existent products in the marketplace today, Microsoft, Google, existent tethered PHRs, that we should be able to get to level one with minor tweaks of existent applications and essentially existent policies. But as you start to get to level two, that's where we get a little infrastructure, a little more policy, and in level three, significant infrastructure and significant policy.

Carl Gunter – University of Illinois – Professor
Even in level one we would need to clarify some of the other steps that are not in the pictures, like how information gets from a PHR back to a physician.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
We purposely left that out because we assumed that once it got up to the PHR it was outside the domain of regulated healthcare. That's why I agree with John completely that we assumed that the infrastructure that would be in the untethered PHR would be up to the commercial entity that was running it because it would be outside the realm of regulated healthcare.

Carl Gunter – University of Illinois – Professor
If the PHR is just to sync where data goes to sit, it will not be an exchange system between providers.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Right, but I would agree with Paul that we still do need to attend to the UEL at level one.

Paul Egerman – Software Entrepreneur
Right, the benefit of the level one is it makes progress on the UEL. It's because Carl's comment is right is one of the things that makes level one feasible. In other words, this is not really about exchange between

providers. It's exchange from the EHR into the PHR. Then what happens to it after that is up to the patient. Again, part of what makes it feasible from a policy standpoint is the patient's in control. In other words, the data in one model gets downloaded directly to the patient at the patient's request. So if the patient's requesting it for each transaction, for example, then a lot of the policy issues become a lot simpler. Once it gets to the PHR, it's up to the patient what he or she wants to do with it. They can just accumulate it for their own monitoring purposes. They can print it out and hand it to a physician. Whether or not an EHR could consume an electronic version of that is unknown right now, maybe some systems can, but that's the purpose for level one is to get it to the PHR so that at least patients can have access to it and they can print it out or use it for whatever purposes they want.

John Halamka – Harvard Medical School – Chief Information Officer
Right, because we know that stage one of meaningful use requires that a certified EHR be able to import a CCR or CCD and display it as human readable. What we don't have is a definition of how one transports it from the PHR to the EHR. So that could be the use of a direct protocol, it could be a thumb drive, it could be a DVD, and as Dixie said, we didn't specify the mechanism of transport, although obviously in the future we would certainly like to see some standard apply so that EHR and PHR vendors could build an ecosystem without having ambiguity.

Gary Marchionini – University of North Carolina – Dean & Professor
I want to jump in on this part because it seems to me that ultimately people do want to upload things that are data that they're collecting personally in their homes, for example, from monitoring devices, sensors, what have you, to selected EHRs that are distributed to certain physicians. So is that a level two kind of function then that we're thinking about in this model?

John Halamka – Harvard Medical School – Chief Information Officer
We didn't specifically address that use case. To me, assuming that we were in the future going to gather home care device data and patient provided or sourced data as stage two might require, that is probably a transaction that could benefit from a UEL wrapper and a kind of directed push like NHIN Direct provides.

Paul Egerman – Software Entrepreneur
... like a messaging transaction, right?

John Halamka – Harvard Medical School – Chief Information Officer
Yes, the only thing I guess you could think about from a level two perspective is if the patient needed to discover the address of their doctor in the act of pushing a set of data. It's just really more a directed push transaction like level one more than it is so much level two.

Gary Marchionini – University of North Carolina – Dean & Professor
Okay, thank you.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
One of the things that would be I think very useful to flesh out before the final version of this comes out is what, if anything, is able to be done by declarative statement and what it is that requires procedural knowledge. A lot of what we're talking about here it sounds like is people at the keyboards trying to type the right set of commands to the right set of places to make things happen. But an awful lot of what has to happen that's traditional standard, the normal kinds of things that people would like to do, could be done by declaration. For example, you could have lists of people that could access various things, where various data needs to be sent and the like, and to the extent that it's just a normal transaction that would just happen automatically behind the scenes. For those things that don't work like that, then you'd need to know specifically what keys to type, what places to send, find the addresses and whatever. It's just not clear as it's currently laid out here how much of the system is actually declarative and how much is procedural. So that would be good to clarify, I think.

Paul Egerman – Software Entrepreneur
Okay, that's helpful.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Although we assumed in putting these use cases together that the untethered PHR was really outside the scope of the PCAST regulated environment, I think we probably should make that really clear that—my opinion is that we're not going to require that every Microsoft and Google in the world implement a UEL push capability. But rather at the provider end if they want to pull information or if they want to receive information from PHR and incorporate it into their EHR, that that side, that's where the UEL would come into play and they would need to map it into a UEL.

Paul Egerman – Software Entrepreneur
Good comments, and we'll talk about that a little bit more in a minute. I have a couple of questions. One is I've put back on the screen the definitions, and we see this definition of atomic, "the smallest meaningful piece of information about a patient," and I guess perhaps as I look at it I underline the word "meaningful." One of the very consistent comments that I see coming back on the entire PCAST Report is this comment about data and context, that if you do data elements too small you lose the context and therefore you lose the clinical meaning. Does this definition of atomic mean that somehow we've addressed that issue, that basically we're saying well, you're not supposed to lose the context of a data element?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
There are probably at least two sub-issues to this. At one level, I think it does solve that, because what you're saying, for instance, to do a simple example, if you just store a number like 37 into somebody's record it has no meaning. If you store a label that says "hematocrit" and 37, if you store those two pieces it's actually still not meaningful because you need to know the date and time. But if you store basically for a patient the fact that this is a hematocrit measurement and the value associated with the measurement and the date and time it was done, it's probably now meaningful, at least in some context. The other part then comes in, which is to say, okay, but if you want to safely use that data you may require that you state whether this was the pre-op hematocrit or the postop or other things, and now you're into where essentially where it's sufficient is very dependent upon the use case.

So I think there are two levels in here. One that says is it understandable, I at least know enough information that for some use cases this is good and in other use cases I don't. So this is a little bit tangential but you understand that you can actually name something. Say it's let's change the temperatures or heart rates or something, instead of hematocrits, and say you can label something as the "admitting blood pressure" or the "admitting white count," or that sort of thing. But you realize that the way reality exists is that you have a whole bunch of things that are happening at different times in the patient's record. If you wanted to be crazy about it, you could name something and say this was the heart rate that was 23 minutes after the patient was transported, or this was the dose of medication that was 64 minutes before they went into surgery. The richest context is to know the comprehensive record of time stamped activities that happened. I think once you cross the minimum level of information you're now into use case specific situations to know whether this data is safe to use for my use case for what I'm trying to do with it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think that we make more of the word "atomic" than we should. I just went back to the PCAST Report and that word is used once in this entire report. The phrase that it's used in is that, "The exchange language must facilitate the exchange of metadata tagged elements at a more atomic and disaggregated level." I think, and also in our hearing we heard testimony that the PCAST would recognize that data elements, which is what they focused on, not atomic, would be at multiple levels of granularity. I personally see no reason to focus on the word "atomic." I think that we should be focusing on granularity of data elements and the fact that a data element can occur at multiple levels of granularity depending on the need.

Paul Egerman – Software Entrepreneur
That is very helpful.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I agree with that. My understanding of that statement in the report was that they were trying to make a distinction between saying exchange today happens sort of at the level of asking for a CCD document or something else. I took that statement to mean nothing more or less than you should be able, in this infrastructure, to search for hematocrits, white counts, heart rates, temperatures, not just a vital signs panel or a CCD document.

M
The answer is it could be all of the above, that is, it could be a document, that's an atom. It could be an entire problem list, that's an atom. Or it could be that your problem is history of coronary artery disease, that's an atom. It depends on the context and the need. So, as Dixie said, rather than try to worry too much about atomic, by simply saying it is that level of data granularity that makes sense for the need, that is an atom.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It is a data element. They don't even use the term "atom." They use the term "data element."

M
Yes.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
I guess for anyone, or for someone like John Halamka, how complex does this get from this standpoint? So in the current world the faxing and paper documents, when I request information in an emergency department we'll fax a request that says we want all the radiographic studies for the past three months, or we want the most recent hospital discharge summary with labs and radiology information. Then we'll get faxed those complete documents for those things, when the patient signs a consent and we fax that back and forth to the sending facility.

In this instance, in order to define these things, if you take a chemistry panel that has 12 discrete data points in it—a sodium, a potassium, a chloride and so on—when you define these things you could define a chemistry panel as an atomic unit or a meaningful piece of information. Or you could define each individual discrete lab result as a meaningful piece of information. But it seems to me that two questions arise. One is, how much more complexity and work does it create the smaller you make those pieces. Then number two, I think that this definition of "atomic" it is useful because it very clearly gives a definition that makes sense to me. But it's also useless because it really doesn't define for a specific thing, and using my example in the chemistry panel, are we going to define that as the full chemistry panel result for that particular test, or are we going to define it as the individual components of that chemistry panel. Does that make sense, the question I'm asking?

John Halamka – Harvard Medical School – Chief Information Officer
Oh, absolutely. If you think about the way a CCD is organized today, a CCD will have a section that is a results section. Within the results section it will have a LOINC encoded laboratory result, which is a discrete data element. However, in reality, you'd want the value of the lab, the unit of measure of the lab, the fluid and maybe even the means of the analysis, so the definition of an atom there would probably be four data elements, not just sodium was 140-something. So, sure the query language becomes complex and the server which delivers the data becomes more complex the more granular you get, so one of the things that I would imagine over time is that this is an evolution. It may start off that information servers are going to provide episode of care documents, that's as granular as they can get, and maybe they're after a piece of an episode of care document, lab results, and then maybe they're after the serum sodium unit of measure fluid and means of gathering or analyzing.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
You're exactly right. But just to be clear too, for data to participate in the kind of decision logic, at least as I would hope we can support with this, you need to have fine grain discrete data, and in fact we're not asking systems to go to a level of granularity they don't already have in most cases. Most hospital information systems, electronic medical record systems, are storing data at a discrete level, especially for

laboratory data, temperatures, heart rates, all of those kinds of things. So it is an increasing complexity to be able to query that through the UEL, but the data exists inherently as those atomic pieces in most systems.

Jonathan Perlin – Hospital Corporation of America – CMO & President
It exists in those atomic pieces. I just want to point out that there's no such thing as a standard panel, unless that's defined somewhere else. So the standard metabolic panel at hospital A may not be in hospital B or practice C. I'm agreeing with everything that John and Stan have said, that the other is that there are all sorts of oddities that may be nuanced in a particular environment and it's nice to have the source of the sodium because you sure wouldn't want to employ a serum sodium from a urine sodium or some other fluid sodium.

Paul Egerman – Software Entrepreneur
That's a great comment, Jonathan. I'm wondering, again, as I read through the materials one of the things that was suggested that needs to be done is create an organization called a "Naming Authority," which I assume will be involved with naming the metadata, and I'm wondering if that's a vehicle to start to address some of the issues that you just raised.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think it is. I think the harder part is going to be the practicing authority. When you represent peripheral pulses, as an example, and the doctor feels arms, legs or whatever for the pulse, the conventions, as great it would be to be able to describe those peripheral pulses in a consistent way, and admittedly a metaphor that's paper-based but then it's translated electronically is that some people draw a number of pluses. Some people write 3+, some people PPP, peripheral pulses present, peripheral pulses intact, and so it can be very difficult. Obviously, a computer can do a piece of the work, but those naming conventions would be a start. The broader challenge would be the implementation to comport to that.

John Halamka – Harvard Medical School – Chief Information Officer
Unfortunately, I have to drop off, but I will follow you guys asynchronously by e-mail.

Paul Egerman – Software Entrepreneur
Terrific, thanks.

Stephen Ondra – NeHC – Senior Policy Advisor
As I listen to this, I think that a couple of thoughts come to mind. First, I think the definition around what is an atomic element makes a lot of sense, because it is not all that specific. Second, in terms of naming conventions ... to the data will evolve over time, and it will evolve and each type of data will have different sizes and evolutions on this. So starting with things fairly broad in general, so you may have in the use case a lab, something that is at a higher, larger level of lab inclusion than will be in end state, but it's a starting state. It will be the kind of thing that you start with molecules and then you go to atoms and then you go to subatomic particles. This is an evolving process and I think starting with the very broad definition of meaningful and then zeroing in on, okay, what is the lowest common denominator, and then evolving that to more specific makes a lot of sense.

Paul Egerman – Software Entrepreneur
Those are helpful comments. I appreciate the discussion. I'm also looking at the time and I feel I need to move to the next topic of our agenda, as John Halamka said that he and I think all the taskforce members will be available for e-mail questions. But before we move on, I also had an observation. In listening to the whole discussion, Bob Kahn's comment about the declarative statements and his comments about how you do query language, I heard Dixie's comment about how audit trails would be handled, and there was just this very recent, very useful discussion with John Halamka and Steve Ondra about the definition of meaningful. My question is, in our report should we have two or three or four pages perhaps in the appendix, some of these technical explanations as to how this all is intended to work. Because it seems like we're starting to gather some interesting knowledge here and we've got a lot of academic people on the phone, but we'd like to be able to somehow transmit that to ONC and perhaps to other people.

Hunt Blair – OVHA – Deputy Director
Paul, I think that's an excellent suggestion. I think, moreover, that the taskforce is really to be congratulated, because the remarkable work you've done in this short period of time has transformed the discussion that we're able to have from abstractions to some very real and tangible—even I'm actually able to follow along with this at a level that is not totally incomprehensible to me. So it's fabulous and I think that being able to then document in the way that you just suggested, Paul, would be really great. I think that just the overall comment that I wanted to make about the work that's been presented to us is that I think it really hits the mark in terms of being able to present ONC, a vision of where we are now with health information exchange, the verb, and how we could be evolving towards a future vision of that. So just huge congratulations to everybody who did that work.

Paul Egerman – Software Entrepreneur
I think that's great. I think if it's okay with everybody, first, I want to echo what you just said, Hunt. The people who worked on the Implementation Taskforce really did a great job, the 15 categories, the progression, organized the way to think about this. The first use case we're going to return to in a few minutes because it's going to help us decide what we want to do with stage two. So this is excellent work. So I agree, we need to say thank you. After saying thank you, I think what I'm going to do is ask you to do more work, which is to see if you can write this short explanatory document, and I'm wondering if we could draft you, Bob Kahn, to help us do that, if you think it's a good thing to do. It just seems like there's a lot of helpful information that came out of this question and answer that I think we ought to summarize somewhat.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
I'm happy to help if somebody gives me specific direction.

Paul Egerman – Software Entrepreneur
We will do that. I appreciate that.

W
If you want, I'm volunteering Doug, who just stepped out and walked back in the room, but you may want to talk with Doug as well. He might be able to help you to—

Paul Egerman – Software Entrepreneur
Yes, what we can probably do is Doug can help us too. What we really first need is an outline of the topics that would be included, but the group might be able to do that also. So again, it was an extremely helpful discussion. If you remember our agenda, there were two taskforces. The first was Implementation Taskforce and the second one was the Policy Taskforce. So now I'm going to do a quick report on the Policy Taskforce. I also—

Leslie Harris – Center for Democracy & Technology – President & CEO
Can I just make one short point on implementation before we leave it?

Paul Egerman – Software Entrepreneur
Sure, although I bet you're about to say what I'm about to say, but why don't you go ahead, Leslie.

Leslie Harris – Center for Democracy & Technology – President & CEO
No, I probably am not. I noticed that throughout the document the references to patient consent are framed that the data, there's always going to be a consent tag. This is one of the problems with our dealing with the PCAST Report, but I just want to make sure we don't put out documents that make it look like we're changing policy. I think the consent references maybe we change to "applicable consent" or "required consent" because not every use case requires consent. Unless we're seeking to change policy, which I think is not our job, then we need to just be careful about that.

Paul Egerman – Software Entrepreneur
Actually, that was not what I was going to say—

Leslie Harris – Center for Democracy & Technology – President & CEO
I know.

Paul Egerman – Software Entrepreneur
—and that is a helpful comment, so thank you.

Leslie Harris – Center for Democracy & Technology – President & CEO
Okay.

Paul Egerman – Software Entrepreneur
On to the Policy Taskforce, and again we're changing agenda topics. Also, normally we would have presented the Policy Taskforce first in front of the technology. We did it in the sequence we did mainly because, as you can tell, both Bill Stead and John Halamka had time constraints and we really wanted both of them involved in the discussion. Now, the Policy Taskforce basically approached things from a different direction, so whereas the Implementation Taskforce was trying to do was to structure things and to actually come up with some specific solutions, the Policy Taskforce, to paraphrase something that Leslie said in one of her e-mails, our job was just to spot policy issues. We weren't trying to solve the issues. We sort of are saying here is where an issue is that needs to be solved.

Now, one of the things that we saw as we did this is something that was seen by the Implementation Taskforce, which is that each of the policy issues are themselves interrelated, so decision making one place affects the decision you make someplace else. The Implementation Taskforce saw the exact same thing, the decision they made in one area of the framework would affect something else that they made in another area of the framework. Then clearly also what happens with the technology side and the policy side is very closely interrelated. In other words, policy and technology are always interrelated, but it seems this is particularly the case here, that there's a lot of impact back and forth.

So what you see on this screen, the Policy Group came up with actually I think it was nine topics that we spotted, and for each topic we tried to say what was the somewhat relative importance of the topic, and we also made some very brief comments about the implications of the topic. What you see on your screen are the ones that the group thought was the top three, and so I'm going to go through this quickly and then I'll do the next six.

The first one was privacy and security. So you put that up and that's probably obvious to everyone. That's got to be the number one topic, because that's clearly in the feedback. There are issues about privacy, as was suggested earlier, about the aspects of getting access to the metadata; there are issues about how granular the privacy will be. So there's a number of issues there and the clear implications that we wrote about it is this is like fundamental and would have an implication to consumer satisfaction or patient satisfaction and adoption as possibly an impact on clinical processes, administrative processes. There are structural issues. By structural, I mean how you actually organize these things. So there are huge impacts to how that decision is made or those policies are determined.

The second area that we identified as a major area, I wrote this down as "Multi-Patient, Multi-Entity Analyses." It's one of these things, I had trouble actually finding the right title for this, so if somebody could help me title this better, that would be very helpful because I wanted to say research, but that doesn't work. Population health doesn't work. So I wrote this down. In one place I wrote down "Ultra Large Analyses," and in another place I wrote down "Large," so I'm not sure I titled it right. But it's really the issue of using this data for purposes that are not clinical purposes. When we talk about this data, we're accustomed to talking about secondary uses of data. The reason I didn't call it "Secondary Uses of Data" is if the subject that we're talking about is what is the relative priority of that data, somehow when you say what is the priority of secondary uses you're starting to answer the question by phrasing the question that way. Because certainly the word "secondary," at least to me, implies a priority, so I wasn't sure of the right title, but we put in this category a series of issues, which is the issue about what is the priority of doing this. Does it have an impact on clinical processes, which are considered to be the primary use of the data? There are the issues that relate to privacy, to consent involved with these

analyses. There are all the issues with de-identified data and re-identified data, so we packaged that together and so that was a major topic.

The third major topic that the task group said was governance, and again in governance there are a number of issues put together. We also acknowledge that ONC has started a governance function but there are just issues about who's going to do the governance, how are entities or organizations or individuals going to be held accountable for what they do, and also the organization of these entities that are called record locator services or the DS. That was the governance issue. Then I'm going to quickly go to the next issues and then pause and let people make comments.

On the next series of six, we have this EHR/PHR issue. This was written up to reflect the issues that you, Dixie, touched on in your previous comments. There was an observation made that the way the PCAST Report seems to be organized is the PHR data and the EHR data are merged together. If that's the case there are some policy implications of that as it relates to HIPAA and security and privacy and to what extent all of that has to go from the EHR systems to also including PHR. In the discussion of that issue there was an alternative given, which is to make these two completely separate, in which case you would have separate approaches to each. Again, as things are interrelated, if you take the separate approach the observation was that that might have an impact on issues like how you handle granular privacy decisions because you might have different approaches for the PHR and the EHR.

There was the issue, number two, you see of the record locator service, also called DS, and one person I think correctly asked me is it service or services, because they thought it should be plural, talking about the entities themselves that provide this indexing and directory services, and we broke that into two components. One was a component where we were looking at authentication and role-based access that say well, there are policies that need to be written there so who can access the indexes and based on the roles if there's any limitations as to what they're allowed to do.

The other interesting issue is the record locator service, among the other issues, is who can do it, what kind of organization can be a DS. The group put forward three alternatives. One alternative is that the DS or record locator service could be a government agency, so that could be like a public health agency. But it could also be the new insurance exchanges, which everyone gets confused between insurance exchange and information exchange, so an odd solution to that problem would probably be to actually make them one thing so it ends the confusion at least. One possibility is government.

The second possibility is a business associate, so that would be the HIE organizations that currently exist. The third possibility that was mentioned was covered entities, or large IDNs, or accountable care organizations, so perhaps a network of covered entities could provide the record locator service.
Third was overexposure, a very interesting issue. The idea is when you're doing searches for data what are the policies about what happens when you accidentally or inadvertently get more data than what you wanted? More data in the sense of extra patients or more data in the sense of you're looking for one thing on a patient, you're looking for mammograms, and you end up with ankle x-rays, what are the obligations? Under what circumstances do you need to notify a patient?

Number four, data holder responsibilities and liabilities, this is a very interesting discussion. So we've said in this whole policy environment what happens, what are our responsibilities if you are a record holder, if you hold an EHR system and in particular, what level of autonomy do you have. Can you say, well, I don't really want everybody to have access to my data; I want only certain people to have access. Do you have any responsibility to prevent some people from having access, even beyond what's included in the DES.

Then there were the liability questions that are asked, in particular is questions about malpractice liability. How does this impact the record holder's liability. The implication on this issue that's very, very interesting, though, that was put forward is sort of a reminder to everybody that our entire program is voluntary, that this is not a mandatory program. Physicians and hospitals have a choice as to whether or not they want to participate. So the observation is how you handle the issue of responsibilities and liability could possibly impact adoption. In other words, if there's too much liability and there's too much

responsibilities people might say I don't want to do that, which is counter to what we want to accomplish. This is not necessarily an easy issue.

Number five is education transparency, which is partly interrelated to some of the issues related to privacy and choice in patients, but it's also just related to the issue of adoption, that you have this increasingly complex environment and presumably people need to understand it if we want them to participate. The last one, a very interesting issue, is the regulatory status of metadata. What makes that a very interesting issue is well, just what is that status. You've got data, then we've got this other thing called metadata and does it follow the same rules as data in the regulations. So you have to keep track of who accessed it, what happens if somebody changes it, do you have to keep track of the changes, do patients have any rights to request corrections to metadata, what happens if somebody wants to change the provenance data, are they allowed to do that. There's a whole series of interesting issues as it relates to the metadata.

I tried to, very briefly, go through all this, and I probably spoke a mile a minute. So let me stop and see first if the task group members have any comments that they want to add, if you feel I missed something or you just have any comments that you'd like to add.

Gary Marchionini – University of North Carolina – Dean & Professor
I think in the first slide where we talk about the big three overarching issues, in a sense that first one of privacy and security is also about control, and a lot of the control issues or ownership, if you will, fall out in the others. Do we need to say anything specifically about control or ownership as an overarching?

Paul Egerman – Software Entrepreneur
Well, it's up to you. You tell me.

Gary Marchionini – University of North Carolina – Dean & Professor
What I'm wondering is privacy and security and control might be a little bit more inclusive, because then on the next set of slides that does come up, certainly in the liability kinds of points for sure, but even elsewhere.

Paul Egerman – Software Entrepreneur
When you say "control," you're talking about control of the content and the record control over what's exchanged?

Gary Marchionini – University of North Carolina – Dean & Professor
Yes. Well, both, because it could be the actual primary data, it could be the metadata, or even the ability to access at all three of those levels. Some of this has to do with some of our discussion about EHRs, in that the EHRs tend to be owned, if you will, by the providers and then secondarily by payers and maybe even in a tertiary fashion by the patients, whereas, the PHRs pretty clearly are owned by the patients. So I see that as an overarching issue for the PHR/EHR point, for the point about any legality and also responsibilities and liability, and even in the record locator service I think there are issues of control. I don't know, it's a small point.

Paul Egerman – Software Entrepreneur
I think it's a great point. Unless somebody objects, I don't have any problem with it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Paul—

M
Paul, I have a question. Is the PHR owned by the patient, or is it owned by the IT company that's hosting the PHR?

Gary Marchionini – University of North Carolina – Dean & Professor

When I think of my PHR, it's owned by me, and that's the way I think most people would want to think about it, because I might be putting personal comments, annotations, that I don't want anybody else necessarily to see and I'm having some trust in whoever it is, Google, Microsoft, whatever. But I really think that most people are going to want to believe they own it.

Leslie Harris – Center for Democracy & Technology – President & CEO
I think it's important to say "believe." We have no mandates and we have no laws that apply any specific privacy rules to PHRs, and whether or not you own it or whether or not they could do something else with the data depends entirely on their policy too.

M
I have a major question related to level one from the technical group, which is that given that we're in a space where there's not any clear ownership regulations that an approach to information exchange that's based on pushing things out of the protection areas is questionable from a policy perspective.

Paul Egerman – Software Entrepreneur
I don't think it's questionable if it's done at the patient's request. In other words, the concept, at least right now for the PHR, is just an issue of if I'm a patient and if I want a copy of my record, on paper I can get that. If I want an electronic copy I can get that also according to the regs.

Joy Pritts – ONC – Chief Privacy Officer
Paul, I find that conversation about PHR interesting because it's a topic that's near and dear to my heart. But I think it's straying a little bit from what we really need to talk about today, which is what are the aspects of PCAST that present either unique or heightened concerns that are different than other methods of exchange. So if we could identify those, that would be very helpful.

Paul Egerman – Software Entrepreneur
That's correct. For everybody, Joy Pritts is the Chief Privacy Officer at ONC. I hope I get your title right, Joy.

Joy Pritts – ONC – Chief Privacy Officer
That's it.

Paul Egerman – Software Entrepreneur
To respond, Joy, to the extent that that's a topic that we listed—we recently listed that as a topic—is our interpretation of the PCAST Report has a merger between the EHR and the PHR system, which is unique to the PCAST Report, so that data elements from PHRs could be published in effect in this sort of Internet process and would be viewable intermixed with EHR data. So we felt that raised some policy issues, and as Leslie suggested also, what we basically said was that raises policy issues, and there are some policy issues about the EHR/PHR whether they're merged or whether they're separate that probably need to be articulated.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Paul, I don't think all of us assumed that. I don't think that everybody on the Implementation Taskforce necessarily assumed that. I personally assumed that the PHR, as I mentioned earlier, was outside the regulated realm entirely, so you wouldn't have data flowing back into the system, or at least this architecture wouldn't address that.

Paul Egerman – Software Entrepreneur
That's correct, at least at level one it does not.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I don't think it does at any level.

Leslie Harris – Center for Democracy & Technology – President & CEO
I agree, Dixie. I just don't know. I couldn't tell what it did to the separation between the two.

Paul Egerman – Software Entrepreneur
Let's put it this way, if it says that it's merged then there's an issue and that should be addressed.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, and obviously it's not clear, so it should be addressed. This is an excellent set of issues. I commend you guys for coming up with these. An additional consideration, I won't say it's a concern, that came up in our discussions of the Implementation was the patient's rights to know what of their information is indexed in the DS and who's actually using it, you know who's actually accessing their metadata. I guess this addresses your metadata issue, but do they have a right to see what in their data, what information is indexed and who is accessing their metadata?

Paul Egerman – Software Entrepreneur
Great question. That is what we're trying to say with this issue of regulatory status and metadata. Again, I'm not sure that's the correct title, but is there an audit trail of who's accessed it, do patients have the right to look at it, do patients have the right to look for corrections to that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The PCAST Report says that there's an audit of access to it. Good topic.

Paul Egerman – Software Entrepreneur
Do we have other comments about the policy issues?

Joy Pritts – ONC – Chief Privacy Officer
Is there any question about the policy issue, about the amount of volume of metadata that's actually cached? Personally, I think that's one of the things that distinguishes the PCAST approach from other record locator services.

Paul Egerman – Software Entrepreneur
The way we addressed this so far in the documentation is at two levels. One is to say there's this section about well, what's the status of metadata. Because there's a lot of it, is that the same as data, you need some new regulations about that. Then we do have places where we're looking at what are the responsibilities of the data holders.

Joy Pritts – ONC – Chief Privacy Officer
Right, but that just assumes that there's a certain amount of data in the metadata tag. So I guess I'm raising it up one level to say because of this approach is there a policy issue about how much data should be included in the metadata tag?

Paul Egerman – Software Entrepreneur
That's a good question, and I think we have a little bit of that but probably not as clearly as you just asked that, Joy, and we can add that to the list.

Leslie Harris – Center for Democracy & Technology – President & CEO
Right, which was the question that I kept posing, perhaps too early—

Paul Egerman – Software Entrepreneur
I'm sorry. I didn't hear the last comment. Who was speaking?

Leslie Harris – Center for Democracy & Technology – President & CEO
I said that was the question that I kept asking, perhaps too early during the implementation discussion.

Carl Gunter – University of Illinois – Professor
It seems like how much information is in the metadata seems like the core question here I see coming out, the problem being that even the tiniest bit of information of this kind can seem very sensitive at times.

Paul Egerman – Software Entrepreneur
That's correct.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
Paul, I wanted to raise one question, and it came up several times with one of the ONC meetings in particular, and that was the issue of identifiers for patients and the ... issue of triangulation. Everybody seemed to agree at that meeting that if you don't have some kind of unique way of getting to the patient's information, you're just not going to know that you got the right information or you know how to get there. But the policy at the federal level has been there shall be no patient identifier issuance in the form of things like social security or the like. As I understood the discussion there, everybody was saying, yes, but we know how to get around that by triangulation because we'll look at where it was coming from and what kind of symptoms they have, and we can figure out a unique identifier from all of that. Shouldn't that be one of the issues that is actually a policy discussion issue? I realize that one of the things we were asked not to do was to go critique the actual report, but it seems to me that it's such a fundamental issue and I was just wondering if it isn't worth some discussion somewhere in one of the topics under policy.

Paul Egerman – Software Entrepreneur
Good comment, Bob. Here's the situation, we do have this topic that's on your screen, number three, overexposure, which is the issue of what happens if you're looking for a patient whose name is Robert Kahn and you see the wrong Robert Kahn because there's a different spelling of the first or last name or something. So that's the issue of overexposure and misidentification of data and what are the circumstances under which you have to notify the incorrect patient, and there might be other issues. In terms of the identifier itself, it's like a third rail or something.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
I know.

Paul Egerman – Software Entrepreneur
The actual law says that HHS cannot spend any money looking at a universal patient identifier. So since they can't spend any money on it, it doesn't make sense for us to make any recommendations on that issue. It's more of a legislative issue than it is an issue that HHS can handle.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
That says even though it is a substantive issue, certainly as far as the technical community is concerned, we just put blinders on and just don't even mention it because of that.

Paul Egerman – Software Entrepreneur
Well, I think what we do is we look at stage two of meaningful use, and you've got to realize that to the extent there would ever be any progress on it, it's a multi-year issue and I think we've got to work with the environment we've got.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
But this isn't being paid for out of HHS money or the like, and it seems to me this group could say whatever it felt was appropriate to provide in the way of feedback. Even if we think the policy is wrong we could state that, or if we had a better suggestion we could state that, or we could at least point out that it still remains an issue, and it seems to me that would probably be a worthwhile thing to do rather than just keep—

Joy Pritts – ONC – Chief Privacy Officer
Since the charge of this group is to ..., to the extent that you think correctly identifying patients is an issue that seems to be a broad and general issue that seems like it might be appropriate it would be helpful. But it's the same issue that's come up before the tiger team and before that NCVHS, and so it is an issue that we're aware of and that's been discussed a lot. So what we're really looking for here is if you see some aspect of PCAST that's a little different than the other ones, that would be really great to know. What is about PCAST that makes that patient matching issue a little different than the other models of exchange that we've already had discussions about?

Carl Gunter – University of Illinois – Professor
One aspect is the PCAST Report envisions a larger scale system, a national system, and so the chances of errors due to a weak identification would perhaps increase.

Paul Egerman – Software Entrepreneur
This is helpful to try to weave this all together. I think what we can do is add to the policy discussion exactly what we just said, is because of the magnitude of the searches, clear patient identification is a policy issue that is reasonable for review. Hopefully, if we put it together correctly, that will be responsive.

This is a great discussion. I particularly like the discussion from Leslie and also Joy about the quantity of the metadata that we also have, to include that. Are there any other comments about this? Again, keeping in mind we have the luxury in this whole process that we can just spot the issues and we don't have to solve them, which is a great position to be in. Although, you run the risk if you say too much about any issue you might be on a workgroup that actually has to solve it, which could be interesting discussions. Any other comments in terms of looking at this and saying what did we miss that we should include?

The way that we're going to handle this, I think, in the final document is we're going to reference these top three things in the body of the text, and if you saw Section C, you saw a little bit of how I already did that. Then we'll have a little bit more detailed write up about the three in the appendix, along with the other items that are listed. Again to repeat, if somebody could help me, I really could use some help on item number two, multi-patient, multi-entity analysis in terms of wordsmithing the name of that, that would be helpful, to make sure we capture that correctly. So unless anybody has any other comments I'm going to move on to the next item on the agenda.

Hunt Blair – OVHA – Deputy Director
Paul, this is a very quick comment. I just think that the work that's done in the separate document more detailed description of what you've just covered is really quite clear and articulate, and so I hope that the majority of that, in one form or another, will be in the appendix, because I think that, like the other taskforce, this is very valuable, helpful work. My thanks to everyone on the other taskforce as well for your work; this is truly impressive, what's coming out of this.

Paul Egerman – Software Entrepreneur
Thank you very much, Hunt. One thing also, I had asked for some help in wordsmithing number two, but anybody it would be very helpful to read through that whole write up of the privacy and policy topics, making sure that what is written there is clear and correct, and any suggestions will be both appreciated and incorporated. I appreciate that comment.

The next topic on our agenda, and we're doing great on our agenda, is it says on the top of your screen "Section D, Meaningful Use Stage Two." First, I'll explain why it says Section D. To remind you, we have four sections to our report. The first section, Section A, is a very brief description of what the PCAST Report is all about. Section D is a brief description of what the public feedback was. Section C was something that we talked a little bit about at the last meeting. It's what's the end state and how does ONC get to the end state. Section D is a little bit more pragmatic, as it were, so very short term this is what you can do in the next three months or six months. Again, to repeat the comment I made earlier today, the reason that we're having this discussion right now is stage two is on the front burner for ONC right now. The basic processes in March and in April, there's just a lot of discussions going on about this and it's part of an entire cycle of things that need to happen. This is something that is very important to get done.

To also remind you, I don't know if people read the draft write up for Section D is intended to be a straw man approach. The first part of what we said in that document is what we decided at one of the previous meetings that well, stage two could not be a complete, what we call end-to-end. In other words, it cannot be what's in the implementation work plan where you have all of the functions, the DES, you have the granular privacy issues because it just wasn't feasible to get all that done in the time frame. So the

question is, what can we do in stage two that would advance the entire PCAST image that is reasonable? I put down four things on the list.

The first one says, "Push by patient," and when it says push by patient what I was intending here was actually the use case, number one of what you saw in the Implementation Taskforce, and there are really two components to that. One of them is the patient's ability to download data, presumably using a UEL. The second is the patient's capability to request that the provider transmit information through their PHR, presumably using the UEL and perhaps using this transport mechanism, I think it's called Direct. What do people think about that? What we would be doing is listing an alternative, listing that as an alternative for stage two meaningful use to advance the PCAST Report.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think that that's a great idea, Paul. I think that clearly ARRA HITECH requires that if the patient requests it the provider must provide an electronic copy to somebody that the patient requests be provided. I just rechecked stage one included the first part of that HITECH requirement, that the patient be given a copy of their record, but stage one did not include that second part of the HITECH requirement that it be sent to the PHR provider or any other named person. I think that, including sending it to PHR, you already have the regulatory backing that you need to include it in stage two, then I think it fits well with our level one.

Carl Gunter – University of Illinois – Professor
Also, I think along those lines is that given that people are going to be required to do it, having some structure whereby vendors can work around some common way of doing it that is supported by meaningful use and other things would perhaps align everybody's activities better so that it's more efficient.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I would probably rephrase it as "push to PHR."

Paul Egerman – Software Entrepreneur
"Push to PHR" is a better way?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, because given that HITECH requires that providers be able to do it, I think that is the reasonable measure is that the provider actually do that.

Tim Elwell – Misys Open Source Solutions – Vice President
Paul, is that what's intended here, though? I read it that the patient would be able to initiate the record directly to the EHR, so are you looking at a bidirectional type of—

Paul Egerman – Software Entrepreneur
No. I had intended for meaningful use stage two as I wrote it, I intended it as single directional. Obviously if you think it should be bidirectional you can propose that. But that's not what I intended when I wrote it up.

Tim Elwell – Misys Open Source Solutions – Vice President
Is it initiated by the patient from the PHR to the EHR?

Paul Egerman – Software Entrepreneur
Yes. The Implementation Taskforce people can correct me if I've got this wrong, but I picture this as like maybe one or two flavors. One is a patient might look at the patient portal and somehow—

Tim Elwell – Misys Open Source Solutions – Vice President
Right.

Paul Egerman – Software Entrepreneur

—or something and they could download the data themselves and then they could do whatever they want with it.

Tim Elwell – Misys Open Source Solutions – Vice President
Right, that's how I had understood it. Dixie, do you believe that we should look at a bidirectional or would you restate this?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
No, I would say it's single direction, but it's not from the PHR to the EHR.

Paul Egerman – Software Entrepreneur
It's the other way.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think it's the EHR to the PHR.

Paul Egerman – Software Entrepreneur
And, Tim—

Carl Gunter – University of Illinois – Professor
I think you're confusing the transport mechanism with the information flow. I think the information flow is always here intended to be from the EHR to the patient or the patient's PHR. Whereas, the transport protocol, there are a variety of options for how that might work that involve possibly pushing the data or having the patients pull the data. But the information flow has always been envisioned as out of EHR and to the patient.

Paul Egerman – Software Entrepreneur
That's correct. As I was starting to say, we picture there are two flavors or two transports. One was a download directly to the patient. The second flavor, or second transport, was the patient requests that the EHR transmit the data directly to the PHR.

Tim Elwell – Misys Open Source Solutions – Vice President
Got it, okay.

Paul Egerman – Software Entrepreneur
And there would be two different, as the previous speaker said, two different protocols for that. But the idea is that both would presumably involve the UEL, which we're really describing, I think it's called level one in the Implementation Taskforce report, so it would involve those components, all of which appear to exist except there would be a little bit of definition around the UEL itself that needs to occur.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think that that UEL component would be what would differentiate it from stage one, because stage one already requires a push from the EHR to the patient, but it doesn't have the requirement that it be done using a UEL type wrapper. So we could make it both of those, number one that they push it to the patient in the UEL wrapper; and number two, that they be able to push it in a UEL wrapper out to a PHR as well.

Carl Gunter – University of Illinois – Professor
Pursuant to the comments that Joy made, this is also what would be different in a recommendation from existing PHR work with a standardized UEL wrapper that would be used in conjunction with PHRs. I'd like to add that if you do have these UEL wrappers, because of the provenance information it opens the possibility of some sharing of PHR data that we go back into EHRs, because now there's an authentication mechanism for that data so that it has integrity. But the report we have here doesn't say anything about how that might occur.

Paul Egerman – Software Entrepreneur
That's right.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
This is all feasible. Again, my concern would be the time frame. If we're talking about this push happening in a UEL wrapper, that implies then that in the time frame for stage two meaningful use that there is a UEL that has been defined and approved and hopefully prototyped and that we know is fit for purpose. I really question whether that can happen in the time frame of stage two.

Paul Egerman – Software Entrepreneur
Good comment, Stan. We have some Standards Committee members on the call; Dixie, Jonathan, do you have any comments about that?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
When does the NPRM for stage two need to be published?

Paul Egerman – Software Entrepreneur
The issue probably is when does it need to be written, and I think that's over the summer.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think the general time frame is that we certainly want to include the HIT Standards Committee in helping us with some recommendations. If you do the backwards plan, if you will, we need to be able to have everything essentially finalized or at least have a sense for things by September. Which means we would need to have a cycle or two before that in the summertime to have the HIT Policy Committee take a look at it, which means we would have to have completed, vetted and piloted by July.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Whoa!

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I would agree with Stan.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think it's a critical issue and one that I think as we take a look at the various alternatives I think there are a couple of things to think about. The first is what's common across all of the various scenarios that are here that would allow us to begin moving things down the road. I think the table that we've got really helps us think about the components and what's necessary to build from level one to level two to level three. I think one thing is what's common across that, what provides us a path of least regret?

I think the second thing to think about is given the time frame that we have, it's going to be hard for us to start with a completely blank sheet of paper. Starting with a blank sheet of paper has two things associated with it. If you start with a blank sheet of paper, it's hard for people out there that are using other methods of exchange to figure out the migration path, because they don't know how their current way of doing things relates to this new way. So certainly starting from some existing work, it doesn't have to be taking it all en masse, but knowing where we are now and where we want to go I think, one, both helps us with the migration path; and two, I think it helps us accelerate the process because we're not starting with a blank sheet of paper.

I think the other thing is that we really need to think in terms of what are the things that were paramount with this. One is the notion of a UEL. It may be very difficult to get some things out there piloted, but we could also begin taking a look at things like metadata. I think that is another one of the things that came out of the PCAST Report as being an important part of this new infrastructure, and from my read probably is one of those foundational pieces that we need. The question would be, given the time frames that we have, what are the critical elements that we might need with regard to metadata that could potentially build on existing work, maybe not take the entire structure, but at least what we know in terms of the metadata tags, and what would be reasonable to include. So to me, some of the things that could potentially be on the short list are things like what do we need to be able to identify the information and be

able to match it up so that we can provide value to the provider. That may be in scenario one, what are the elements that we would need in a patient portal?

Number two, the simple query response search might require some of the things for being able to aggregate or being able to match up elements that came from different places. There is a lot of discussion around privacy, and so things around granular consent may be something that we can leverage or take a look at. I think the third aspect of this, which is unique in some sense to this, to PCAST, is something about provenance. If I downloaded it from my PHR, when did I do that, who did it; some information that would help you trace it back to the source materials. Our time frames are incredibly aggressive and we'll have to think about what's the path of least regret and what are the things that can build on where we are now and move us in a direction that will help us with PCAST.

Robert Kahn – Corporation for National Research Initiatives – President & CEO
I think it would be also useful to have some sense of what's been done that's similar to this. There is nothing that deals with the medical problem at large, but there have been efforts in other related areas that might be useful. One of the things in particular that I would point out is that there really is a difference between having some kind of a registry structure that can deal with metadata and having all of the defined terms and standards and whatever that go into the defining of the metadata itself. Part of that is the language that's represented, which you obviously would like to be able to change over time as you move from one capability to another.

The other is the syntax and semantics of what you actually say within the metadata and what it means, but there's also the base technology for just dealing with the registry stuff. There are a lot of ones that I know of. We've been involved in building several of them. We built one for the DoD that they use every day. We built one for the entertainment industry. It's used by the cable industry and by the Hollywood studios. We've built one for the publishing industry, which is widely used for all the medical journals, as well as other scientific journals. I think it's worth taking a look at those and seeing whether there's something in those existing approaches that can be applied here, because I think it will save you a lot of time in trying to reinvent the wheel.

Paul Egerman – Software Entrepreneur
Those are great comments, Bob. I appreciate those comments. I want to make sure that for this part of the discussion that we're very focused on meaningful use stage two, and if I heard Doug's comments correctly, basically in order to make it into meaningful use stage two everything needs to be known sometime over the summer in order to start writing regs by September 1st. So the question is, when we go back to this concept of push to PHR, the idea of the patient being able to download data in some sort of UEL wrapper, which the patient then potentially could upload to the PHR, to the question that Stan asked, is that feasible that we could get that done in stage two?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Paul, I think pushing clinical data in electronic form from an EHR to a PHR can be done in stage two and, as I said, given it's backed by regulation we don't need any more policy around that. But if you look at the table that the Implementation Workgroup created, the UEL, we define the UEL as containing three metadata elements: identity, provenance, and privacy. Honestly, we don't have a common UEL metadata model already in place. We don't have common adopted terminology to use to populate those metadata fields at this point. I think a true UEL is not feasible by stage two.

Carl Gunter – University of Illinois – Professor
The UEL seems pretty ambitious, but there is a piece of the UEL that might be more feasible, namely the part concerning the provenance. Basically every mechanism that we've discussed is going to require some sort of authentication infrastructure. If you could at least have the PHRs be digitally signed with a non-reputable certificate as part of a certificate infrastructure that's nationally recognized, something we're actually pretty close to being able to do, that would be a significant advance that's going to be required for every approach that we've discussed.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Then I would tell you that we on the Privacy and Security Standards Workgroup, we're just preparing. At the end of this month, we will be presenting to the Standards Committee our recommendations for digital certificate standard to be developed by the Standards and Interoperability framework team, and we also are making some recommendations on public ... infrastructure type things. But even today in our country you know as we're implementing direct exchanges and NHIN or NW-HIN exchanges, we're proceeding on two different PKIs. So I think, although I totally agree with you that's the direction we need to head, I think even that is not feasible to have achieved by stage two. I think it's more a better target for Stage 3.

Paul Egerman – Software Entrepreneur
I'm confused by this discussion, because I thought the Implementation Taskforce was saying that they could do the first use case in stage two because that was, for the most part, existing—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Except once you dig down into the UEL, to ... it to PHR, yes, I think it's achievable.

Carl Gunter – University of Illinois – Professor
But to put a proposition here, if you can't do authentication I'm not sure there's anything else you're going to be able to do.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
And I'm agreeing.

Paul Egerman – Software Entrepreneur
What are you saying? I missed it.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I agree with Dixie that even with the authentication the standards are not in place and there aren't implementations in place. This thing has to be locked down so that you have a specification that people can start programming against come later this year. All of these things are doable, they're wonderful things, but the timeline is not just right, that you can have enough public input, you can have people prototype it and prove that it works. There's no question that it will work, but there's also no question that we're going to learn something as we try to implement. The difference I see is it is what we mean by this push by patient, because what we could do is say, and it actually is already implied by what's been approved, is that you have to be able to send a CCD document using LOINC codes and SNOMED codes to a PHR. But that is probably doable. What isn't doable, as soon as you say that it's actually in a UEL wrapper or that we're actually moving towards the PCAST approach with the UEL, that's what makes it not doable by July.

Carl Gunter – University of Illinois – Professor
But digital signatures and the UEL are not the same thing. If you can't do anything on authentication or anything on security within meaningful use two, I think that's the kind of poor state of affairs that maybe ought to be looked at.

M
It may be a poor state of affairs, but I think that's exactly where we're at.

Paul Egerman – Software Entrepreneur
Let's put it this way, one of the concerns I have is as I look at the PCAST Report and one of the things it says very clearly, which we already identified, was we were supposed to act boldly, ONC's supposed to be very aggressive. So what I'd like to understand is, if we wanted to do the first use case in the Implementation Taskforce in stage two, what would be the components that would need to be in place for that to occur?

Carl Gunter – University of Illinois – Professor
In a funny sense, you look at the VA's implementation of the blue button, then if we don't care about the security and we don't care about the interoperability it's already possible to do this pretty easily.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
When it comes to the patient portal, even without blue button we already have PHRs that are able to accommodate structured text. John Halamka actually demonstrated using the Direct protocol, it was on his blog, that showed how he was able to send structured information using the Direct protocol to his PHR. So we know that that works. I guess the question I would have for the group is, to me the difference between what John Halamka did as part of demonstrating the connection in a structured way to his PHR and what PCAST proposes, is that it doesn't want to have, say, a document. It wants to have more granular data. One of the questions that I would have is, are there specific kinds of granular metadata that could be applied to use existing mechanisms of exchanging information that would say, I'm not going to send an entire CCR or an entire CCD. What I'm going to do is I'm going to break it into its trunks and I'm going to demonstrate that I can reassemble it on the other end, because I have enough information related to provenance, enough information related to patient identification, and enough information related to granular consent.

Paul Egerman – Software Entrepreneur
What are you suggesting we do for stage two then, Doug? I didn't quite understand that.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
If you had some information that you wanted to exchange in a more granular way that to me is sort of a fundamental point of the PCAST Report. I'm thinking off the top of my head here, just to try to sort it through, so I don't know if I have it all clear. But suppose I had an EHR that could generate a CCD or CCR—and that's certainly part of what we have for stage one meaningful use. If I wanted to take that and break that down so that rather than sending a section that included, say, medications, it was able to actually do that at a granular level that said here is a medication that this particular patient is on. It includes enough information around that atomic element so that I could determine that that was prescribed by a particular doctor or that it was a—

Paul Egerman – Software Entrepreneur
And that's going to be sent to the PHR?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
What's that?

Paul Egerman – Software Entrepreneur
That data is sent to who?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
It could be the PHR in setting one.

Paul Egerman – Software Entrepreneur
What's the use case where the PHR would want that granular data, or where that would occur?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I guess we're trying to demonstrate in some way some of the fundamental building blocks of PCAST, even though we don't have the DEAS or the entire infrastructure, since we've leveraging some of that work.

Jodi Daniel – ONC – Director Office of Policy & Research
From the consumer perspective, so I'm looking at how we get patient ... specific data, and how we get data to be useful. I would—and again, just sort of playing off of Doug and thinking about this—think that if there were particular more atomic data elements that could be then leveraged by PHR innovator consumer folks who are developing consumer facing tools, it could be helpful in providing better information to patients. Rather than the group level data to be able to—

Paul Egerman – Software Entrepreneur

So let's get back to the—

Jodi Daniel – ONC – Director Office of Policy & Research
Again, we don't have the what will it accomplish, but in a PCAST-ian world having the atomic data elements can enable innovation to provide better information to consumers, not just data.

Paul Egerman – Software Entrepreneur
So let's get back to the concept of what it says in number one, "Push by patient to the PHR." The concern there is we can't get this UEL envelope defined. So in other words, what it said in the Implementation Taskforce was that somehow there was going to be some envelope around a CCD and the whole thing was going to be pushed to the patient. So to say there's not time to do that, so my question is, if there's not time to do that, how is there time to do a single data element?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I agree with you, Paul, we don't have a use case for that. I think there's a need for two things. What we're talking now is stage two meaningful use measures, but that's not the only mechanism. We could do what Doug suggested as a proof of concept. But I think requiring everybody who is adopting EHRs to be able to do that I don't think is realistic or could be backed by a reasonable use case.

Paul Egerman – Software Entrepreneur
To get back to the first one, push to the PHR, if I'm hearing Doug and Jodi correctly, we should not include that in stage two meaningful use. Is that correct?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I don't know. I guess the push to a PHR is something that is possible in stage two meaningful use, just because we've already defined some standards in terms of documents about how those transactions might occur. What I was saying is that there have been people, like John Halamka, who have demonstrated using the Direct protocol and using a CCR he was able to push information from his electronic health record to a PHR and in sense satisfy use case number one. The difference, though, is that if you use the existing structures he didn't have that atomic level information and the other things like provenance and granular consent and things like that.

Carl Gunter – University of Illinois – Professor
Also concerning John's demonstration, it's kind of a one-off. He showed how to do it for one provider and one PHR, and that's somewhat different from a national infrastructure that everybody could do something like that.

Paul Egerman – Software Entrepreneur
Right, so I'm trying to understand, what are we saying about stage two? Are we saying that there's nothing that can be done in stage two as it relates to the PCAST Report?

M
That would be my view. In terms of what you require for people to get incentives, there are a whole bunch of things that we can do, in terms of making prototypes and creating the language. But in terms of what you would require people to do to get the incentive money, I just don't see how we can do anything in stage two.

Paul Egerman – Software Entrepreneur
Well let me .... The reason I'm pushing this a little bit is because the report said the ONC's supposed to act aggressively. One way to understand also, however, the meaningful use stage two requirements is that there are two types of requirements, there are core requirements and there are menu requirements. The core requirements are something everybody has to do. The menu is you can choose to do one or two or three of those, and there are some rules as to what you can choose to do. My question is, what would you think about including something like this as part of the menu? If people can do it, great, maybe they're not required to do it and they can do other things for an information exchange requirement.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Paul, I understand this discussion that's been going on, but I'm confused overall in this regard. First of all, whether this can be done or not done is really a matter of whether the vendors and the technology make it accessible. So for stage two meaningful use I'm not quite clear how—I understand that you can say upon patient request a provider must provide an electronic copy of a CCD pushed out to a PHR. I can understand that. Now, how it's done, whether it's with a UEL envelope or whether it's some traditional means or not, the provider community doesn't have a dog in that fight. It has to be what the technology does. So, one, this is really a standards kind of discussion or a technology, is it possible. Two, I don't think it's likely to happen on the timeline for stage two. Three, there's some other facets that came up that are policy sort of issues about being able to push out data in a more granular fashion.

Now, in a query and retrieve kind of mode where an individual who has authority, a patient about their own data perhaps can query something specific and pull it from a multi-source kind of environment, that's one thing. But I guess, again, the use case aspect of this, what do those who have talked about this envision would happen that a doctor or a patient would— I mean, if there's any kind of human component that's involved where you're getting requests for people, "Send me this one medication information. Doctor, send me this one lab result," and a human has to be involved, there's no human workforce in the country that is going to be able to keep up with that kind of specialization.

Paul Egerman – Software Entrepreneur
Yes, I agree. So again the first use case that was proposed was the patient was having access to their portal and then the patient could decide to download data themselves, in which case what they would get would be a CCD, which is already defined, with some sort of UEL wrapper. The UEL wrapper has information, say, about provenance in it. That was proposed. What I'm hearing from Doug and Jodi is that that's not practical to do in stage two.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I guess one other question that I would have is what would be the metadata that you think would be required as part of that UEL wrapper?

Carl Gunter – University of Illinois – Professor
For that I think it would be almost nothing.

Paul Egerman – Software Entrepreneur
I thought the Implementation Taskforce already defined that.

Carl Gunter – University of Illinois – Professor
Level three has the complex metadata but—

Paul Egerman – Software Entrepreneur
I'm talking about level one.

Carl Gunter – University of Illinois – Professor
—level one is pretty simple.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
If you have the ability—and I know that with the description that you have on the table with the UEL syntax, this notion of having an outer wrapper for transport with the inner structure and the various blocks, clearly a standard around what that UEL looks like currently doesn't exist. It probably will take us some time to develop that, but the metadata that would have to be on that tether, if you will, or around that UEL, ... like identity, provenance, and privacy. So to the notion of who it is so you can match it with other stuff, provenance about where it came from, and privacy, which would be granular consent, and it sounds to me like that may be things that could be tractable anyway to at least identify what needs to be included and what that might look like.

Carl Gunter – University of Illinois – Professor

I thought that at least the provenance of something you could push for, because that's going to be in there no matter what and there's already a lot of ongoing effort on how to do that that is in ... those things can be accelerated.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
If all the provider is doing is pushing it to either the patient or the PHR, then the privacy rule is that the patient has authorized sharing with that PHR. So that's pretty simple for that particular use case as well. I think what Stan said earlier would be feasible for stage two, and that is to just push a CCD over to a PHR.

Paul Egerman – Software Entrepreneur
Yes, which is what the use case is, right?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, and I agree that that's already well within what we've specified.

Paul Egerman – Software Entrepreneur
And push a CCD to a PHR with version one of the metadata that defines identity and provenance.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, provenance and the fact that they've authorized sharing with that PHR.

Paul Egerman – Software Entrepreneur
That even might be—

Carl Gunter – University of Illinois – Professor
That's right, you'd be in a good position if you could just have a signed CCD. That would already put us a long way along that path.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, good point.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I agree with that. Again, just recognize that it's moving towards PCAST because now we're including elements that are defined in PCAST, but again the part that I think is not feasible is if you make the requirement that that be in an UEL wrapper, because I just don't think we have the time to define the UEL wrapper. But using existing standards and existing technology you could push the CCD, and you could require in that transaction elements of either security or provenance data, and identity that move us towards PCAST. But it is movement towards PCAST. It's not PCAST yet because we haven't defined the standard UEL wrapper for that.

Carl Gunter – University of Illinois – Professor
One of the things about pushing off some of these atomic data discussions, for example, looking at the digital signatures, there are clever cryptographic techniques of doing signatures on components of documents, so you could put a signature that can be used that also was a signature on any piece of the document that you want. So one could explore those techniques for assisting the atomic transmission of the data after the signature has been affixed, if you don't want to do the other thing of breaking up into a bunch of pieces and giving them separately.

Paul Egerman – Software Entrepreneur
I want to talk about the atomic. It felt like we were close to agreement on something, which was that we can do this PHR download or push under the patient control with—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I don't agree with that. I think that patient authorization, but there's—

Paul Egerman – Software Entrepreneur
Patient authorization, okay.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

Paul Egerman – Software Entrepreneur
Patient authorization and that we add metadata that has identity and provenance and maybe version 1.0 of privacy just that the patient authorized this. That that would maybe stop a little bit short of a UEL wrapper, but that would be a step forward on the PCAST Report and that would be feasible in stage two.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, I agree.

Paul Egerman – Software Entrepreneur
Do we have agreement on that?

Carl Gunter – University of Illinois – Professor
Version … of the UEL seems like a good step forward. One could view it as real progress.

Paul Egerman – Software Entrepreneur
Okay. So that's like an option. Now, I want to go to the issue that Doug raised, and I think it was Carl, I couldn't quite tell, about doing something more granular. So if you look at this slide, if you look at number three, immunizations, if you recall what I wrote for Section D, I said, well, immunizations could be something that could be done on a granular level. That maybe what you do is you take state mandated childhood immunizations and you push that to public health agencies or variations would be to choose a single data element, I don't know what it would be, flu-like symptoms, some single data element. So the question is, is there something like that that's feasible for stage two? First of all, am I rephrasing your comments correctly, Doug, in terms of looking at a single data element?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Well, I think in the previous discussions, what it sounds to me is if the notion is to put a wrapper around the CCD you're defining the granular data element as that document.

Paul Egerman – Software Entrepreneur
That's correct, which we said according to what we said when we did the first discussion with Bill Stead that that's allowed.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, and one could also suppose that the subsections within a CCD could be considered granular elements as well. I'm not sure if you would need more information, you probably would, with regard to a more granular element. Maybe what you've got is you've got the entire CCD as an atomic element, if you will, sort of the element of interest, and you could have subsections and then you could also have a specific data element. So you could have the whole CCD, the section on medications, and then just a particular medication.

Paul Egerman – Software Entrepreneur
Right, and so what I'm asking right now is, is there anything we can do in stage two that's just pointed towards a single data element, like a particular medication or a particular immunization? So what was written in Section D and what was discussed a little bit when we met on February 16th was well maybe we can do this for legally mandated childhood immunizations and transmit them with some sort of UEL structure. So my question is, is that feasible for stage two, or what we said about the UEL wrappers, such that, gee, we really can't do that much for stage two.

M

That's what I would say, Paul. Again, you can do the kind of communication we talked about. When you say that we want to do it in the UEL wrapper, that's the thing I don't think we can get done by July.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think what we're saying is that we could incorporate within the CCD the metadata that ultimately would migrate to the UEL regarding provenance authorization, I guess.

Paul Egerman – Software Entrepreneur
Let me see if I'm understanding this right. I've got on the screen these four things, push by patient, simple search and immunizations, and we said that we could do the patient PHR step forward. It's not going to be a full UEL wrapper. We haven't talked about simple search, but I'm taking a guess if we have all these UEL issues we're far away from doing simple search in stage two and we're saying no to immunizations also. Is that correct? Am I interpreting the conversation correctly?

M
Yes. That's my feeling at least.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

Paul Egerman – Software Entrepreneur
Okay, so the question is for stage two, besides what we talked about for PHR, we're talking about stage two of meaningful use, is there anything else that should be described as an alternative that would advance the PCAST architecture?

M
Again, I've been thinking about your proposal that could we put an option up there, have it be one of the menu options rather than a required element, and that's intriguing. The problem is, again, that even to have it be an optional menu item you have to define what it is. I think we're kind of in trouble there again because the definition of these things and having public input on it and really raising the level of knowledge and capability around this problem. It's not that there aren't some people in the world that wouldn't know how to do this now, it's adopting that as a general solution through an open public process. It's not a technical problem, as much as it is one of education and supporting an open process to adopt this. So if you made it a menu item anyway, the best I could think about that is that you almost make the menu item say something like participate with ONC in prototyping a PCAST approach.

Gary Marchionini – University of North Carolina – Dean & Professor
I like that. I was actually thinking about something similar, if we could make one of the options be participate in some of this prototyping or pilot testing that we had talked about in some of the earlier meetings, as being one of the likely realistic things that might get done. That would be, I think, an attractive option because it would force providers who weren't perhaps ready to take a full lead and try something themselves, to at least make some kind of act of participation. They might be a test site, or they might build a piece of the system, and that would give people a little bit of room to move and still participate.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Who does anyone really think is going to have any interest in doing this? The provider community, why would they care to do this? The menu options are things like there are a whole array of things that ONC and the government would like providers to do, but not every one of them is applicable to every provider, so from these pick ones that are most germane to your thing. This is something that ONC or CMS would put an RFP out to some vendors and say would you like to be a pilot for testing this between your technology and us. I don't see how this is germane specifically to making it a menu item for the provider community. I don't get that.

M

The incentive would be to actually be a part of actually testing whatever perhaps some vendor put together. It's like trying to get subjects to participate in your study, you try to incentivize that somehow. This might be a kind of incentive to get some providers to collaborate or cooperate with the people who are actually developing those prototypes or tests.

Paul Egerman – Software Entrepreneur
Here's an idea, I think what we have to do is run this by ONC that the observation I give, it's kind of tough to write the regulations around participating in a pilot unless you define what the pilots themselves are or the test beds are. The other observation I have is there's probably a vehicle to do this anyway. Which is if there's some provider that's participating, they're exchanging data with a different format or something, I suspect there's a way that ONC would give them some exception or something against some other meaningful use criteria. Because I think ONC has ways to grant exceptions or, I don't know what the right wording is, but say you don't have to do A, B, and C for the following reasons. I think that exists. Another way to look at my question is instead of looking at the pilots, to look at what would be, to pick up what Steve said, in terms of things that a large number of providers, eligible providers or hospitals could participate in. It sounds like other than the PHR concept we don't have anything specific right now to suggest, is that correct?

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
I think that's true.

Paul Egerman – Software Entrepreneur
I want to ask this question, again, a little bit differently, which is to recall at the last Policy Committee meeting where David Blumenthal said that there was a lot of policy makers who were concerned that ONC might be spending money that would be in the wrong direction. I don't think he used the word "wasted," but that was the impression I have is that, gee, if you move forward and you do things in a certain way and then later on you're going to do it with this PCAST approach, you will have wasted money. That of course a lot of reasons why one doesn't want to do that. So my question is, is there anything that we want to tell ONC or Doug that they should not do in stage two that we think would be a direction away from PCAST?

Carl Gunter – University of Illinois – Professor
I worry about—I don't know if this is going to be much on meaningful use, but—programs that encourage the states to move forward with solutions that are not integrated is a worrying direction compared to PCAST, because then if you want to have a national system you'll have a lot of entrenched interest.

Hunt Blair – OVHA – Deputy Director
Can you say a little bit more about what you mean by that?

Carl Gunter – University of Illinois – Professor
Yes, there's a program for the state health information exchanges and all the states are looking to develop their own programs, and they are developing different programs. This is great in terms of experimentation, but when you go to do a national program as the PCAST Report envisions you're going to have then people who have already done a fair amount of work developing their own state program and they're going to not want to switch.

Hunt Blair – OVHA – Deputy Director
Right, so thanks for that clarification. So I guess the comment that I'd make—because I'm responsible for one of those programs—is that going back to a comment that Doug made a while ago. It would be, and under the heading of path of least regret, it would be helpful and maybe we've just determined through our discussion that this doesn't tie directly to stage two of meaningful use, but it does tie to the overall directionality of where we think things could or should be headed. To think through what the implications are for state level exchanges further down the horizon, which I think, Carl, is what you're saying, in a PCAST-ian universe. So that seems like it would be a fruitful topic because my take from what the Implementation Workgroup presented, is that, and I think that John Halamka alluded to this, that there is

a sequence from where we are now and where we could go where the directionality could be directed with the state players. So I'm not sure how we implement that, but I think it would be good to express.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, I think we're at a potential tipping point relative to the state programs, where they could all be aligned so that they're all helpful towards the common goal. Or we could be spending money to move down a disaggregated path where people have competing techniques that they don't want to give up because they've already committed to them.

Paul Egerman – Software Entrepreneur
Sorry, who just spoke?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think it's going to be a challenge on this call to solve that particular problem. I think we all would probably agree, and I think people have talked about it before, about the notion of an ultra large scale system that will, by definition, have different parts of the system in different paths of evolution. I think we have to recognize that that's likely going to be the case, and I think whatever we can do to continue to converge is going to be important, but I don't think we're all going to be able to move in lock-step even if we had that vision and could roll that out.

I think that having been said, we've talked a lot about different approaches, and I know that some of the early discussions on this call with regard to PCAST talked about, Paul, in fact, presented it at the last Policy Committee, this notion of top-down, bottom-up, and middle-out. Middle-out is to say what are the fundamental building blocks that we need that are somewhat independent of whether you have a state HIE that has a utility model versus one that uses Direct, versus one that uses a PCAST approach. I think when I take a look at the recommendations and the thoughtful analysis that this group has done, even within the use cases that you've described, we know that we're going to have to have something around metadata tags and ways of identifying and marking up the information so that we can have machine readable ways of dealing with that. That could be something like the CCR, the CCD, or it could be even more granular as we drill down with PCAST, and that's independent of the kinds of architecture that we might have.

I think we also know that things like having some security infrastructure around certificates or the like is something you need for direct exchange, for things that are using the NW-HIN specifications, and something that we know we'll need for PCAST. Even things like enterprise level provider directories, I know it's not listed in use case number one, but it's something that shows up in use case number two and certainly is another one of those common set of building blocks.

So I completely agree with you that there are things that we need to do to make sure that we continue to align the work, but one of the things I think this group can help, because you guys have already had some of those discussions, is what are the fundamental building blocks? What are the equivalent of HTTPS, HTML, DNS, TLC, all the things that we use in the Internet that allows us to exchange information. Are there things here, and I would suggest perhaps that PCAST is telling us we need a UEL, something that will allow us to describe this information and some semantics around it, and then there are some other implied pieces, like the DEAS and others, that are part of those building blocks. So I recognize the concern and we do have to continually work to make sure that our programs are aligned, but there are things I think that we can do that can help guide the states and help guide the other programs in identifying what these building blocks should be.

Paul Egerman – Software Entrepreneur
That's helpful. What you're saying is in terms of this path of least regret, I sort of asked my question in a negative way, what shouldn't ONC do; a better way would have been to ask it in a positive way, which is what should they do to make sure that we have this vision? Part of what I'm hearing you say, Doug, is to create the building blocks. So again, even as it relates to the state programs if we know what the building blocks are, and the state programs are doing the building blocks, then we know we're advancing things. Am I hearing that correctly?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, I think that's really one of the pieces that this group can provide in terms of value to the states, it may be something that we need to make sure that we've got authoritative directories for entities or authoritative directories for providers. It may be that we don't have that immediately, but that's something that would certainly, something for meaningful use stage two, but it may be something that we need to provide some direction about what those building blocks are. From my perspective based on the discussions that you've had, there are some fundamental things that are common across all the use cases and that probably are common across even other ways of doing exchange.

Paul Egerman – Software Entrepreneur
Okay, so helpful comments. I want to talk a little bit more about the building blocks in a minute, but I want to make sure that I wrap up this discussion of stage two of meaningful use. One of the things I wanted to call the attention to the workgroup to is in stage two of meaningful use. Of course we don't know what it will look like, but one of the things that happened in stage one of meaningful use is we had these various push transactions, like laboratory results, and what is likely to occur in stage two of meaningful use is that those will continue and they're likely to be expanded. Expanded meaning well, something was before done, like you had to do 40% of your lab results in one way and that might jump to 80%, or if something was in the menu it might go into the core. So what I also wanted to see if we could clarify is since we already said that the push transactions were foundational, I'd like to be able to clarify that if that occurs in stage two of meaningful use we don't view that as a step away from PCAST. In other words, that's not work that we're going to regret later on in the expansion of the push transactions that might occur from stage one to stage two. That's a good thing. Are people comfortable with that concept?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I would need to go back and look at the specific, I mean, there were a lot of measures in stage one, so I think that it would be worthwhile to go back and look at them specifically from that perspective.

Paul Egerman – Software Entrepreneur
Yes, because I think in terms of the argument that we can have, that would be one value to look at that and to either flag anything that we are concerned about, or to say, well, it's fine. In other words, what we want to do is say this is what needs to happen in stage two and we want to reassure people that there's nothing else that's happening in stage two that is something that people are going to regret later. So you say you want to look at that, and I'm trying to understand what is the best way to do that, should we just ask people individually to look at that? Should we ask the taskforce to go through it? How should I approach that issue?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I've extracted the table from the regulation, it's not that long, maybe I can send that to you, Paul, and just everybody could just give it a quick look over.

Paul Egerman – Software Entrepreneur
Yes, that would be great. If you could extract the table and do exactly what you said, and if we could all look at that, and then we'd be in a position to make a comment in our report that says we looked at it and what we've seen so far is either okay or here are the places where we have a concern.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Paul, Steve Posnack has developed a very, very nice table that's available on the ONC Web site that really steps through the policy objectives, the criteria, the standards, essentially a summary of all of meaningful use stage one. I'm happy to forward that to you and you can forward that on to the committee if you find that useful.

Paul Egerman – Software Entrepreneur
Yes, that would be great. Again, what I'm really looking at for stage two is what is being proposed for stage two for information exchange, and is there anything there that would be on the path of regret, or,

can we say it's all fine? That's what I would be looking for. Does that make sense? Is that usable to you, Doug?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, I think that this particular chart doesn't go into stage two meaningful use, I mean, obviously there was an Implementation Workgroup yesterday that began stepping through some of the—

Paul Egerman – Software Entrepreneur
Yes, I sat through most of that.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
—..., and that presentation may also be helpful.

Paul Egerman – Software Entrepreneur
Yes, so what we should do is, there are three things. One is, Dixie, you said that you're going to try to look at this—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It sounds like the table that Doug mentioned might even be better, because I just plain pulled it out of the federal register.

Paul Egerman – Software Entrepreneur
Yes, but Doug's table is about stage one.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
That's what mine is, it's from stage one. I don't think we have stage two yet, right?

Paul Egerman – Software Entrepreneur
We've got a summary that was done yesterday, so that's probably what I need to do is pull that together.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

Paul Egerman – Software Entrepreneur
I looked at it briefly and, as I say, it was things like expanding laboratory transactions. But I just think it's worthwhile for us to pull it together and for people to look at it. I think we've wrapped up the topic of stage two. Does anybody else have anything else they want to say on stage two?

Now, Doug raised this issue of top-down, bottom-up, middle-out, and I had originally intended to start talking about that by looking at the top-down model, but Doug's actually started with the building blocks model, which is the middle-out model. What you're suggesting, Doug, is that what we really could do is give you an inventory of the building blocks that are needed for PCAST, did I understand that correctly?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, and in fact I think that the table that you have with the various components probably has a lot of those elements in there already.

Carl Gunter – University of Illinois – Professor
One thing is that we were urged to move the PCAST vision along with meaningful use criteria. As we discussed the meaningful use criteria, that might help the PCAST Report. We encounter organizations that have been working on things that are related to those, for example, Dixie was mentioning some of the ones that were working on authentication. We might want to have some outreach to some of those organizations to see if we can modify their behavior or accelerate their activities or whatever would be necessary in order to come up with something useful in time for the deadlines to promote PCAST, the parts of it that we're aiming for.

Paul Egerman – Software Entrepreneur
That's helpful. That's exactly right, because once we say what we want for stage two that will have a cascading impact. In other words, that will cause the different groups to complete their work, although I think everyone is trying to complete their work around this April time frame. I'm involved in some of the authentication work and indeed people are working hard to try to get that done by mid-April.

Getting back to Doug's comment about the inventory of the building blocks, we have the 15 categories, but there's some additional building blocks, and you mentioned like the directory services. I'm trying to understand what's the best process to get you what you're asking for, Doug. Shall we ask the Implementation Taskforce to have a phone call, or exchange some e-mails or something to produce that? Is that responsive to what you're saying?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, I think so. It's something, and I've actually started going through it just to see what the implicit assumptions are that underlie some of the recommendations for level one, two, and three, just to see if I could understand what were the building blocks that underline the components that were there. Even though there are 15 or so components listed in the table, some of them say we need a UEL and there are I think four or five that talk about that. So that may be one of the components is a syntax for doing that, another component is going to be the semantic pieces of what the value sets or what the attributes are that we care about with regard to identity and provenance and things like that. It may be that the implementation ... just sort of takes that and do a rough pass at what they think might be necessary.

Paul Egerman – Software Entrepreneur
Great. Then, as I say, I want to wrap up the discussion of stage two of meaningful use. As it relates to stage two meaningful use and as it relates to the state programs, the way I'm understanding this discussion is that basically part of the value of these building blocks is that that gives affirmative direction as we move forward. As long as we're building towards this vision and the building blocks we're on the path of least regret.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, I think so. It doesn't mean that there may not be work that needs to be done. So, for example, somebody could create a directory that has some of the information necessary but not all of it, but the fact that they have a directory that's separate from some other infrastructure makes it easier to swap out one building block and put in another. So it's not the panacea, it's not going to entirely future-proof things, but it certainly is different than if we say let's build a top-down architecture and now we've chosen something that is different than the way in which PCAST looks at things. To me it's the difference between an AOL approach to the Web early on, versus what has evolved over time with the various components that come together to allow Amazon.com to be successful.

Paul Egerman – Software Entrepreneur
It makes sense.

Hunt Blair – OVHA – Deputy Director
I think, Doug, everything that you just said and said previously makes a lot of sense. I would just say from the point of view of the state programs—well, I will only speak for my own state program, but I think some of my peers would be heartened to have a discussion about building blocks, even if they can't be fully articulated. They can't be fully articulated, but pointing in the direction of understanding that there are lots of different experiments that are going to happen that we are trying somehow to converge, and this ties back to the discussion of the Information Exchange Workgroup earlier in the week. I think that any signals, signs, pointers that we can collectively place out there will be helpful.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, I would reflect that. I have the impression some of the state programs are looking for some help and guidance that they just don't have to decide everything themselves within their own state.

Paul Egerman – Software Entrepreneur

That's great. That's a terrific discussion. So what we've done in the agenda is I think we have gotten through the sense of what we need to do for Section D, Doug made reference to top-down, bottom-up, and middle-out, which are the parts of Section C. When we started the call I said that if we actually got through that we would get extra credit and a star or something. The basic issue is, again, if you think through the organization and the final report, there is this Section C that talks about the end state vision and then talks about how ONC might go about approaching it and then it talks about these three approaches. One is very aggressive, basically ONC imposes things. A second approach is an approach where it lets the companies and private approaches do things and multiple approaches compete. And the third approach is more like this building block approach that's called middle-out that Doug was just talking about. So there's some statements made in that Section C about that and in the next slide it shows top-down actions. These are all straw men actions, and so my reason for introducing this is simply to say that would be the major topic of what we're going to do in our final meeting next week is to review that material to see how we might want to improve and edit it.

What we're going to be doing in the interim is I'm going to do my best to take all of this material, we've got some action items that we've got to do on stage two meaningful use, but before March 30th we'll actually have a draft of the entire report for you to review and comment on. But in my opinion we're making really excellent progress. This has been a terrific call. So we're close to the point where we should be opening the call for public comments, but let me pause and see if people have additional observations or questions or comments.

Terrific, well, I hope everyone understands the direction we're heading. But I want to say again this has been huge progress, so I want to thank everybody for their efforts today. Judy Sparrow, if we can, let's open the lines and see if members of the public would like to make any comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
Operator, can you check with the public and see if anybody wishes to make a comment?

Operator
We do have a public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Can you please identify yourself?

M
Hi, this is ... from .... I'd like to commend the Implementation Taskforce for their stage-based approach. A couple of comments on the transmission to PHRs, as everyone knows, they come with the potential modification by the patients and hence digital signatures was a good idea. In terms of pushing the PHRs, the ... can be pushed to the PHRs without need for granular consent. It's when you pull from the PHR that you need to worry about the granular consent. So that's just a thought to leave there.

The other thing is that at ... we have implemented PCAST capabilities today, writing on standard IHE protocols and we showed that at HIMSS last month. In particular, we have the ability to index granular discrete data across multiple HIEs from standard CCDs, the ability to provide semantic search capabilities across the CCD data, and the ability to provide patients with the ability to manage their security and privacy. We'd be happy to get the PCAST ... and would be very interested in participating in a pilot should ONC choose to do so.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Mr. …. Do we have any other comments?

Harley Geiger – Center for Democracy & Technology – Policy Counsel
This is Harley Geiger with the Center for Democracy and Technology. I'm sorry that I had to get on a little bit late to fill in for Leslie, but I wanted to make a suggestion about Subsection C, and specifically under the description of the PCAST end state vision, under the first point there. I think that it's worded in such a way that it can be easily misconstrued, and I'm not sure it's a completely accurate statement of what

PCAST said. It says every American will have an electronic health record and will be able to establish privacy rules that limit the way those records are electronically accessed. But we actually think that PCAST had said that it was more based around what the current requirements are. So there's a better way to word it, we think, to avoid that statement being misconstrued ,and so perhaps maybe every American will have electronic health records and will be able to have their privacy preferences for how those records are accessed to honored. And also under the same portion there under the description of PCAST end state vision Subsection 3 makes a reference to certain other individuals and I'm not clear as to which individuals we're referring to there in that document. Those are my comments. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Harley. Any other comments?

Mark Segal – GE Healthcare – Director Government & Industry Affairs
This is Mark Segal.

Judy Sparrow – Office of the National Coordinator – Executive Director
Go ahead, Mark. Hello?

Mark Segal – GE Healthcare – Director Government & Industry Affairs
—and then some real positives. I was concerned that the initial technical discussion didn't really reference current standards or technologies that implement them, and it seemed a bit abstract. I think as you move to the final report it would be helpful, particularly to link it to some of the later discussion around CCD documents and what we've been hearing about IHE profiles. There was, I think, a very good important discussion on the practical implications and timing issues, particularly around stage two, and of what can be done with current CCDs. That timing, as you know, is really critical for our customers and for vendors in terms of safe development.

In terms of a stage two context and what can be done, it may not be specifically part of the meaningful use requirements, but I think there are a lot of opportunities around the use of more advanced IHE profiles like XDS that do involve queries of CCDs. That this can be done, and I think in a sense is being done, and is part of ONC's HIE strategy. This approach would really cover many of the key PCAST roles. The EHR association just recently submitted a document to ONC on how the CCD facilitates metadata at multiple levels within the documents. Provenance and identity should be able to be handled and for consent data I think the sense is that that's best handled not being embedded in the CCD document, but facilitating a pointer to consent information.

Finally, in terms of the work on CCD, I think the ongoing work that Dr. Fridsma is leading with his colleagues on the ONC Standards and Interoperability framework should really be able to look at what can be done with a CCD in terms of multiple levels of meta tagging of data. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Mark. Any other comments? Okay, Paul, I'll turn it back to you.

Paul Egerman – Software Entrepreneur
Great. I just wanted to thank the members of the public. Those are all excellent comments. Your comment, Harley, you actually are a member of the workgroup, or CDT as through Leslie, and the Section C that was sent out was sent out as a straw man draft, so I very much appreciate feedback as to how to clear that up. So feedback from CDT or from anybody else on that topic is—

Harley Geiger – Center for Democracy & Technology – Policy Counsel
Sure. I commented publicly because I didn't know how much of the discussion I had missed and didn't want to interrupt it. But I'd be happy to send you some of our—

Paul Egerman – Software Entrepreneur

Yes, if you can actually send me a red line version of it, because what you said made perfect sense. So I just did my best to write it fast, but when I do that later on I either forget it or I can't read my own writing. So if you could send that to me, that would be very helpful.

Harley Geiger – Center for Democracy & Technology – Policy Counsel
Sure, I'd be happy to.

Paul Egerman – Software Entrepreneur
Terrific. Once again, let me say thanks to everybody. First, does anybody else have any comments or questions they want to ask? So let me say thanks, everybody. I especially want to thank the ONC team, Judy Sparrow, Jamie Skipper, Jodi Daniel, Doug Fridsma, and Joy Pritts. I very much appreciate all of your help with today's call. We have one more call on March 30th. We're making terrific progress. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Bye-bye.

Public Comment Received During the Meeting

1. I'm representing the Biomedical Informatics Think Tank. We have a UEL-like method that does not assume that a search requires passing of PHI. In fact identifiers are not necessarily passed in a UEL search result. To start implementing a UEL you need a UEL standard specification. To get such a standard you need to run various pilots to see what works and what doesn't. You should be there by Meaningful Use Stage 3, but not Stage 2. PCAST Workgroup should be proposing areas where pilots should be run, e.g. search, security & privacy, aggregation, etc. Target a UEL Standard Spec within two years. Also propose areas that Stage 3 might be required to implement UEL, so EHR manufacturers can be watching closely for those areas. Dixie's "proof of concept" is what I mean by pilots. PCAST said ONC should act aggressively, but the majority of commenters said that UEL should not be included in Stage 2. Without the UEL Standard Spec you cannot move towards UEL because you really have no idea about what UEL will look like. Saying that you push EHR information to a PHR as a CCD is not related to PCAST report at all, and I think you shouldn't suggest that it is because it is likely to generate resistance. Even a physician does not need identifiers to treat a patient. I agree that Bill's definition of Atomic is use case-dependent. Atomic needs to remain at the lowest level the data can be divided. The context can assemble these atomic data elements as required. Say "Push by Patient to PHR."

2. I think it is critical to leverage this effort to increase trust - how does Dr. Fridsma's earlier comment regarding increasing granular metadat related to patient consent? I was just pointing out that Doug initially indicated that the PCAST focus related to privacy and security should not be lost if we are attempting to prioritize what we incorp. into MU2 should reflect those things that would increase trust. Increasing the functional scope of consent to support Consumer Privacy Preferences seems to be a double down opportunity. I think the middle out appraoch could encompass the CPP aspects - especially along the vector of the recommendations made by Dr. Mattison at a recent HITPC meeting. If we leverage the response to the recommendations of the PCAST report to Establish the meta-data that would enable his three tier approach to improving Consumer preference configuration may be a realizable goal and aligns with the middle out approach.